SMOKELESS TOBACCO: IMPACT ON THE HEALTH OF OUR NATION'S YOUTH AND USE IN MAJOR LEAGUE BASEBALL

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH OF THE

COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

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TOBACCO: IMPACT SMOKELESS \mathbf{ON} THE HEALTH OF OUR NATION'S YOUTH AND USE IN MAJOR LEAGUE BASEBALL

WEDNESDAY, APRIL 14, 2010

House of Representatives, SUBCOMMITTEE ON HEALTH, COMMITTEE ON ENERGY AND COMMERCE, Washington, DC.

The Subcommittee met, pursuant to call, at 10:08 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Frank Pallone,

Jr. (Chairman of the Subcommittee) presiding.

Members present: Representatives Pallone, Eshoo, Engel, Green, DeGette, Capps, Schakowsky, Matheson, Barrow, Christensen, Sarbanes, Waxman (ex officio), Shimkus, Whitfield, Buyer, Blackburn, Gingrey and Barton (ex officio).

Staff present: Brian Cohen, Counsel; Alvin Banks, Special Assistant; Mitchell Smiley, Special Assistant; Brandon Clark, Minority Professional Staff; Clay Alspach, Minority Counsel, Health; Ryan Long, Minority Chief Counsel, Health, and Aarti Shah, Minority Counsel, Health.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REP-RESENTATIVE IN CONGRESS FROM THE STATE OF NEW JER-

Mr. Pallone. I call the meeting to order.

Today the subcommittee is having a hearing on the prevalence—well, I should say the title of it is "Smokeless Tobacco: Impact on the Health of Our Nation's Youth and Use in Major League Base-

ball," and I will recognize myself for an opening statement.

The subcommittee is examining the prevalence of smokeless tobacco products, diseases linked to the use of these products and the correlation between smokeless tobacco use by youth and Major League Baseball players. This is an important issue of longstanding interest to this committee, and it is my hope we can continue to raise awareness about the dangers of smokeless tobacco and shape future discussions both in Congress and in Major League Baseball.

There are various names for smokeless tobacco. I have to say, I haven't even heard of all of them. It is called spit tobacco, chewing tobacco, chew, chaw, dip, plug and probably many other things unknown to us in this room. But in all forms, the tobacco sits in the mouth while the user sucks on the tobacco juices, spitting off when they get rid of the saliva that builds up, allowing nicotine to be absorbed into the bloodstream without even swallowing. But no matter what name you call it, its use is clearly dangerous to your health.

In the United States, both smoking and smokeless tobacco has long been associated with baseball. In the early days of the 1900s, baseball players chewed it to keep their mouths moist on dry and dusty fields or they would spit it into their gloves to soften up the leather and even use it to prepare the notorious spitball. Then during the 1950s, smoking tobacco became the product of choice. In fact, when baseball games were first broadcast on TV, cigarette ads became prominent features. Smoking was such a part of Major League Baseball that fan loyalty in New York could be identified

merely by what cigarette brand an individual smoked.

In the 1970s, things shifted again as the public became aware of the dangers of smoking and chewing tobacco crept back into baseball. During that time, the smokeless tobacco industry used celebrity baseball players as models in their advertisements, sent free samples to clubhouses in the major leagues, minor leagues and colleges, and ramped up efforts to reach a more youthful audience. As a result, sales rose by 55 percent between 1978 and 1985. Since then, smokeless tobacco use by baseball players appears on TV screens across the United States 7 months out of the year. It doesn't seem too much of a stretch to consider that kids associate tobacco use as part of the game, and perhaps even believe that it is part of the game that enhances an athlete's performance. I could easily imagine a child thinking well, last night Yankee Nick Swisher hit a home run with a wad of chew in his cheek, maybe I can do that too. And the hero phenomenon is a powerful mania that can have profound effects on our children.

My own concern is that smokeless tobacco use in baseball presents a public health risk that extends beyond the baseball players themselves. Millions of teenagers and young adults in the United States use smokeless tobacco. The most recent survey results indicate that over 13 percent of high school boys and over 2 percent of high school girls currently use smokeless tobacco products. In fact, surveys by the Centers for Disease Control and Prevention have found that among high school boys, usage rates of smokeless

tobacco increased by 22 percent between 2003 and 2007.

Now, we all know that tobacco use causes cancer no matter how it is absorbed by the body. Smokeless tobacco is not a safe alternative to smoking, and I am worried that message is not reaching the youth of our country. A 2008 study by the World Health Organization's International Agency for Research on Cancer concluded that smokeless tobacco users have an 80 percent higher risk of developing oral cancer and a 60 percent higher risk of developing pancreatic and esophageal cancer, and despite bans of smokeless tobacco in college and the minor leagues, there is no ban on it in Major League Baseball.

So I look forward to exploring the reasons behind this exception. I am also anxious to hear from our witnesses about their recommendations on how Congress can better address this public health issue, and I would like to thank all of our witnesses for

being here today.

[The prepared statement of Mr. Pallone follows:]

CHAIRMAN FRANK PALLONE, JR.

HEALTH SUBCOMMITTEE HEARING

"Smokeless Tobacco: Impact on the Health of our Nation's Youth and use in Major League Baseball"

OPENING STATEMENT

April 14, 2010

Good Morning. Today the Subcommittee will examine the prevalence of smokeless tobacco products, diseases linked to the use of these products, and the correlation between smokeless tobacco use by youth and Major League Baseball players. This is an important issue of long-standing interest to this Committee. It is my hope we can continue to raise awareness about the dangers of smokeless tobacco and shape future discussions, both in Congress and in Major League Baseball.

Smokeless tobacco is also called spit tobacco, chewing tobacco, chew, chaw, dip, plug, and probably many other things unknown to us in this room. In all forms, the tobacco sits in the mouth while the user sucks on the tobacco juices, spitting often to get rid of the saliva that builds up, allowing nicotine to be absorbed into the bloodstream without even swallowing. But no matter what name you call it, its use is dangerous to your health.

In the United States, both smoking and smokeless tobacco has long been associated with baseball. In the earlier days of the 1900s, baseball players chewed it to keep their mouths moist on dry and dusty fields, spit it into their gloves to soften up the leather, and even used it to prepare the notorious spitball. Then, during the 50s, smoking tobacco became the product of choice. In fact, when baseball games were first broadcast on TV, cigarette ads became prominent features. Smoking was such a part of major league

baseball that fan loyalty in NY could be indentified merely by what cigarette brand an individual smoked.

In the 70s things shifted again as the public became aware of the dangers of smoking and chewing tobacco crept back into baseball.

During that time, the smokeless tobacco industry used celebrity baseball players as models in its advertisements, sent free samples to clubhouses in the Major Leagues, Minor Leagues and colleges and ramped up efforts to reach a more youthful audience. As a result, sales rose by 55 percent between 1978 and 1985.

Since then, smokeless tobacco use by baseball players appears on television screens across the United States 7 months out of the year. It doesn't seem too much of a stretch to consider that kids associate tobacco use as a part of the game, and perhaps even believe that it is part of the game that enhances an athlete's performance. I

could easily imagine a child thinking; "Last night, Yankee Nick Swisher hit a home run with a wad of chew in his cheek. Maybe I can too."

The hero phenomenon is a powerful mania that can have profound affects on our children.

I am concerned that smokeless tobacco use in baseball presents a public health risk that extends beyond the baseball players themselves. Millions of teenagers and young adults in the United States use smokeless tobacco. The most recent survey results indicate that over 13 percent of high school boys and over 2 percent of high school girls currently use smokeless tobacco products. In fact, surveys by the Centers for Disease Control and Prevention have found that among high school boys, usage rates of smokeless tobacco increased by 22 percent between 2003 and 2007.

Tobacco causes cancer, no matter how it is absorbed by the body. Smokeless tobacco is not a safe alternative to smoking and I'm worried that message is not reaching the youth of our nation. A 2008 study from the World Health Organization's International Agency for Research on Cancer concluded that smokeless tobacco users have an 80 percent higher risk of developing oral cancer and a 60 percent higher risk of developing pancreatic and esophageal cancer.

Despite bans of smokeless tobacco in colleges and the minor leagues, there is no ban on in the Major League Baseball. I look forward to exploring the reasons behind this exception. I also am anxious to hear from our witnesses about their recommendations on how Congress can better address this public health issue.

I would like to thank all of our witnesses for being here today. I now recognize our Ranking Member, Mr. Shimkus for five minutes for the purpose of making an opening statement.

Mr. PALLONE. I will recognize the gentleman from Illinois, Mr. Shimkus, for the purpose of making his opening statement.

Mr. Shimkus. Thank you, Mr. Chairman. I ask unanimous consent that my full statement be submitted into the record.

Mr. Pallone. Without objection, so ordered.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. Shimkus. And then I will just briefly summarize. First of all, I want to welcome Gruen Von Behrens, who is from my district. He is a young man who will be testifying about the damages of smokeless tobacco, and I appreciate his testimony and his advocacy. Tobacco use is bad. I think we all know that in America today. We need to continue to tell the message.

As a young kid who wanted to be a baseball player my whole life, of course we get to do that still here in Washington with the Congressional game, but athletes are role models to somebody, and professional baseball has to understand that they are a role model to the next generation of kids, and we want to encourage that good leadership by example style.

I also want to mention and welcome Joe to the committee room. I am a St. Louis area Member of Congress residing in Collinsville, so as a St. Louis boy, we want to welcome you to the committee. I still remember fondly throughout Major League Baseball but es-

pecially in his hometown of St. Louis, Missouri.

We had a master settlement with the tobacco companies that should have paid in \$206 billion over 25 years. The Government Accountability Office states that only 30 percent of the settlement funds went to health care. Travesty number one. Only 3.5 percent of the funds went to tobacco control like smoking cessation and other educational programs. So when money was provided in a settlement to the States to do what we are talking about today, government didn't do their job. Government always overpromises and we always underdeliver, and the master settlement is a perfect example of not delivering on a settlement with the tobacco companies

We have a lot of issues here to face in health care, the recently passed health care bill, 3,000 pages. There are already fixes that need to be done, whether it is preexisting conditions for kids left out until 2014, whether it is the doctor fix, which still hasn't been done which cuts physician payments starting this month. It is going to be extended maybe a month. Can you imagine running a business on calculations of income on a month-to-month basis? That is what we should be dealing with our time today, addressing the health care needs of the country, applauding the work—I am not suggesting that using the bully pulpit to continue to say that tobacco use is not, I am not saying that is not a good use of time. I think when we are in an economy that people are calling the Great Recession and we are looking at ways to create and expand jobs, government underfunding health care delivery in this country or taking away Medicare Advantage from seniors or cutting \$500 billion from Medicare, there is probably a more critical use of our time.

With that, Mr. Chairman, I yield back my time.

[The prepared statement of Mr. Shimkus follows:]

Opening Statement
Honorable Ranking Member John Shimkus
"Smokeless Tobacco: Impact on the Health of our Nation's
Youth and Use in Major League Baseball"
Subcommittee on Health
Wednesday April 14, 2009

Thank you Chairman Pallone. With the 2010 Major

League Baseball season newly upon us I think a lot of our minds
are on summer and our national pastime. Back home people are
all a buzz about the St. Louis Cardinals who look posed to do
well again this season. And even the Chicago Cubs still have a
chance - at least mathematically.

But aside from this excitement that normally surrounds the start of the season I find myself struggling with the timing of holding this hearing today. I certainly believe we must do all we can to prevent everyone, particularly our more impressionable youth from starting any tobacco use. And when it comes to smokeless tobacco attention should certainly be focused on prevention with our youth playing baseball as a target more likely to be exposed to these products.

However, as we sit here just back from time in our districts

I can tell you my constituents are concerns and want

Washington focused on what the massive 3,000 page health

reform legislation is going to mean for them.

When they were promised by the President, "if you like what you have you can keep it." Seniors with Medicare Advantage plans want to know how they are going to keep the plans they have chosen with over \$200 billion cut from the program.

And those enrolled in the CHAMPVA— a health care program for spouses and dependent children of veterans who died, or are profoundly disabled, as a result of military service, they want to know if the new healthcare law does clearly includes them or not.

When it comes to employers, companies small and large have told me they will pay the penalty and force their employees in the exchange, sooner rather than later. This will result in new insurance plans for all employees. For those low income earners it would mean being forced into Medicaid. From private insurance coverage into our dysfunctional and underfunded Medicaid program how is this, "if you like what you have you can keep it?"

Meanwhile with millions more being placed in Medicaid our hospitals and provider community will struggle for proper

reimbursement while facing more cuts and lower reimbursements coming down the line. In Illinois Medicaid is already 280 days behind in payments. Even then they are only paying providers 30 cents on the dollar. Forcing millions of more into Medicaid will only make these problems worse.

At the same time our physicians face a looming 21 percent cut in their reimbursement as we continue to kick the can on a long-term fix. Physicians run small businesses just like anyone else. How can we expect them to pay their bills, hire new employees, and plan for the future on a monthly budget?

Yet, despite these concerns we haven't had a hearing this
Congress or last on a permanent solution to the physician
payment issue. And the only discussion in this committee on
health reform was one hearing with the Secretary of Health and
Human Services.

Even then she refrained from getting into specifics as the legislation had yet to be introduced. As the dust settles and the questions remain, I hope the Chairman can work with our side to now have Secretary Sebelius come back to address some of these concerns on the health reform legislation that is now law.

On the topic at hand, while I appreciate Major League
Baseball and its players association being represented here
today, I hope we can broaden the scope beyond just the impact
they have on smokeless tobacco use among youth.

I myself play baseball for the Republican team under the masterful managerial leadership of Ranking Member Barton. I have played baseball for a long time, but I have never used smokeless tobacco.

If our mutual goal remains decreasing the overall use of harmful tobacco products we should look to build on successes through cessation and education programs.

I find it disheartening that according the GAO states are only using a little under a third of their Master Settlement Agreement funds towards health care costs. Even more alarming is the very small percentage dedicated to prevention, cessation and education programs.

I hope to hear from our government witnesses today from the CDC and NCI on what more they feel could be done to encourage these types of programs at the state level. And if funding is needed, how Congress might take action to ensure Master Settlement Agreement funds are utilized towards these goals. Lastly, I'd like to specifically thank

Gruen (GRARE – IN) Von Behrens from Stewardson, Illinois in my district for being hear. I look forward to hearing more of your story and thoughts on what we can do to end youth from even starting smokeless to bacco use.

Thank you again Mr. Chairman, and I yield back the balance of my time.

Mr. PALLONE. Chairman Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Last year, we passed a law out of this committee that finally was signed by the President, the Family Smoking Prevention and Tobacco Control Act, and it grants FDA authority to regulate content, advertising and marketing of tobacco products in order to protect the public health. This legislation marked a critical step in a long history of efforts to reduce tobacco use by teens, and we have seen progress. Teen smoking rates are down, and while we still have a long way to go, at least that trend is moving in the right direction.

But there is one exception to this improvement, that is smokeless tobacco. With smokeless tobacco, the trends are moving in the

wrong direction, and the tobacco companies know it.

Throughout the 1980s and 1990s, the use of smokeless tobacco by teens declined at about the same rate as cigarette smoking. But over the last few years, the decline in smokeless tobacco use has stagnated, and use has increased. Last year, smokeless tobacco use among 10th graders reached its highest level since 2002. This is a serious health risk. The increased use of smokeless tobacco will mean millions more teens getting hooked on nicotine.

That is why I want to thank you, Chairman Pallone, for holding today's hearing. We will hear from some of the Nation's leading experts in smokeless tobacco use, learn about its risks, and learn

about how to stem the rising tide of use by young people.

Two of our witnesses are not new to this Committee. In 1994, when I was chairman of the Subcommittee on Health and the Environment, I chaired hearings on the health effects of smokeless tobacco. At those hearings, we heard from Dr. Connolly and from Joe Garagiola, both of whom will be testifying today on the second panel. Mr. Garagiola's 1994 testimony discussed the same subject we will focus on today: the impact of tobacco use by Major League Baseball players and how it influences young people. We appreciate the work they have done for decades now to reduce the use of smokeless tobacco by kids and by Major League Baseball players. Unfortunately, Major League Baseball, and the players' union, have yet to take decisive steps to end this terrible scourge. Some progress has been made. In 1993, Commissioner Selig banned smokeless tobacco in minor league clubhouses and dugouts and therefore baseball no longer allows tobacco companies to provide free samples to players. And the league and the union continue to educate players and fund efforts to reduce tobacco use by youth. But at the Major League level, there continues to be no restrictions on the use of smokeless tobacco by players. This means that millions of young fans are exposed on a daily basis to the use of smokeless tobacco by their heroes. The camera shots are relentless. A recent study by Dr. Connolly's colleagues at Harvard found that in just one game of the 2004 World Series, ballplayers provided \$6.4 million worth of free advertising for smokeless tobacco. If you are a Major League Baseball player, and you are chewing tobacco, you can bet that many thousands of young, impressionable ballplayers are watching you chew. Too many of them will take up the habit to be just like you. That is why Major League Baseball and the players association need to take action to end the use of smokeless tobacco by big league players. We are not saying they should ban the players from using it but not to use it when they are in public, when they are on the field. We don't let baseball players in the leagues go stand out there in the field and drink beer. Major League Baseball won't allow them to stand on the field and smoke cigarettes. So why should they be out there in the field in sight of all their fans on television and at the ballpark using smokeless tobacco?

I think that baseball has the opportunity to protect players' health and protect the health of millions of young adults. This committee will continue its vigorous and ongoing oversight of these issues. When Major League Baseball and the union get together and negotiate the next contract, I hope this will be on the table. I don't know why there would be an objection from the players' union to the same rules for Major League Baseball that apply to minor league baseball where they don't allow the use of smokeless tobacco. The protection of young Americans from the ravages of tobacco in all its forms demands no less, and Major League Baseball and its players must step up to the plate to do their part.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Waxman follows:]

Opening Statement Chairman Henry A. Waxman Hearing on "Smokeless Tobacco: Impact on the Health of our Nation's Youth and Use in Major League Baseball."

Last year, the Family Smoking Prevention and Tobacco Control Act was signed into law. It grants the FDA authority to regulate the content, advertising, and marketing of tobacco products in order to protect the public health.

This legislation marked one critical step in a long history of efforts to reduce tobacco use by teens. Today, teen smoking rates are down, and while we still have a long way to go, at least the trend is moving in the right direction.

But there is one exception to this improvement: smokeless tobacco. With smokeless tobacco, the trends are moving in the wrong direction, and the tobacco companies know it. Throughout the 1980s and 1990s, the use of smokeless tobacco by teens declined at about the same rate as cigarette smoking. But over the last few years, the decline in smokeless tobacco use has stagnated, and use has even increased. Last year smokeless tobacco use among 10th graders reached its highest level since 2002.

This is a serious health risk. The increased use of smokeless tobacco will mean millions more teens getting hooked on nicotine.

That's why I want to thank Chairman Pallone for holding today's hearing. We will hear from some of the nation's leading experts in smokeless tobacco use, learn about its risks, and learn about how to stem the rising tide of use among youth.

Two of our witnesses are not new to this Committee. In 1994, as Chairman of the Subcommittee on Health and the Environment, I chaired hearings on the health effects of smokeless tobacco. At those hearings, we heard from Dr. Connolly and from Joe Garagiola, both of whom will be testifying on the second panel today. Mr. Garagiola's 1994 testimony discussed the same subject we will focus on today: the impact of tobacco use by Major League baseball players and its impact on youth.

We appreciate the work they have done for decades now to reduce the use of smokeless tobacco by kids and by Major League baseball players.

Unfortunately, Major League Baseball, and the player's union have yet to take decisive steps to end this terrible scourge.

Some progress has been made. In 1993,
Commissioner Selig banned smokeless tobacco in Minor
League clubhouses and dugouts. Baseball no longer allows
tobacco companies to provide free samples to players. And
the league and the union continue to educate players and
fund efforts to reduce tobacco use by youth.

But at the Major League level, there continues to be no restrictions on the use of smokeless tobacco by players.

This means that millions of young fans are exposed on a daily basis to the use of smokeless tobacco by their heroes. The camera shots are relentless. A recent study by Dr. Connolly's colleagues at Harvard found that in just one game of the 2004 World Series, ballplayers provided \$6.4 million worth of free advertising for smokeless tobacco.

If you're a Major League Baseball player, and you are chewing tobacco, you can bet that many thousands of young, impressionable ballplayers are watching you chew. Too many of them will take up the habit to be just like you.

That's why Major League Baseball and the players' association need to take action to end the use of smokeless tobacco by big league players.

Mr. Manfred and Mr. Prouty: over the next year, you will begin to negotiate a new collective bargaining agreement for Major League baseball and its players. As part of that agreement, you will have the opportunity to make the same decision about smokeless tobacco that you made about cigarettes and cigars decades ago: banning its use by big league players in the dugout and on the field.

You prohibited smoking on and off the field. It's time to prohibit smokeless tobacco on and off the field.

You have the opportunity to protect your players' health ... and to protect the health of millions of young adults.

This Committee will continue its vigorous and ongoing oversight of these issues. The protection of young Americans from the ravages of tobacco – in all its forms – demands no less.

And Major League Baseball and its players must step up to the plate to do their part.

Mr. Pallone. Thank you, Chairman Waxman. I neglected to thank you in the beginning, but I want to now for all you have done over the years to bring to light the problems with smoking and the industry and championing and sponsoring the legislation that has the FDA regulate tobacco use, so you are going back to the 1990s and you have been doing this for so many years, so I just wanted to mention that.

Next is the gentleman from Kentucky, Mr. Whitfield.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENT-ATIVE IN CONGRESS FROM THE COMMONWEALTH OF KEN-TUCKY

Mr. WHITFIELD. Thank you, Mr. Chairman.

Today's hearing is titled "Smokeless Tobacco: Impact on the Health of Our Nation's Youth," and I don't think any of us object to this type of hearing because it is imperative that we explore this issue, but I think it is also important, and I wish that we would be having a hearing on some mechanisms that are already in place that could probably do more on addressing this issue than this hearing would do. And what am I talking about? Well, first of all, I do want to mention that on March 19, 2010, FDA reissued its 1996 rule and this rule becomes effective on June 22, 2010, which will prevent the sale of smokeless tobacco and cigarettes to those under 18 and prohibit distribution of free samples of smokeless tobacco as well. But what am I talking about? I think this hearing that we should be focusing on, for example, the language that was in the stimulus bill, and one of our complaints about some of that legislation was the fact that none of us really knew what was in it, but now are finding out, for example, that in the stimulus bill there is \$650 million appropriated, made available to carry out evidence-based clinical and community-based prevention and wellness strategies. So the federal government is already giving out money to States if these States will use that money to address certain things like sugar in drinks, tobacco products and so forth. And yet none of us really knew anything about that, and I think it would be beneficial to all of us we could get into that in more detail.

The second thing is the House also when it approved the health care bill approved—not only did we authorize but we appropriated \$5 billion between 2010 and 2015 and then \$2 billion a year forever on programs that would allow States to submit application for grants from the federal government. And in those grants, they are doing things like saying that they are going to increase taxes on certain products, that they are going to be involved in zoning in where, for example, tobacco products or other unhealthy products could be marketed. They are also even talking about reducing the density of fast-food establishments, and what does that actually mean? Are we going to be determining where fast-food restaurants are located?

So while this hearing is worthwhile, I think our time would be better spent on examining thoroughly what happened in the stimulus bill and the health care bill and the money appropriated for that relating directly to this issue. Thank you.

Mr. PALLONE. Thank you.

The gentlewoman from California, Ms. Eshoo.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. Eshoo. Good morning, Mr. Chairman. Thank you for holding this hearing on the health impacts of smokeless tobacco, especially its effect on the young people of our country, which I really think goes to the heart of this issue. This committee has spent a great amount of time examining the health risks of smoking, and I am pleased that we are focusing on this issue of smokeless tobacco

today.

While cigarette smoking has declined substantially in our country, which is very good news, especially in the last 10 years, smokeless tobacco use has decreased only slightly over that period. This suggests that smokeless tobacco use is not a substitute for smoking but instead is adding to the number of tobacco users. Increased education and awareness about the health risks of smoking along with tougher regulations have led to a significant decrease in smokers in the United States. This has been a Herculean effort and

I think it really signifies real progress.

As the tobacco industry sees sharp declines in sales, it is obvious that they are looking toward alternative products to hook young customers. Smokeless tobacco is inconspicuous. Kids can use it at school or in class without causing much attention. Smokeless tobacco is also a gateway substance because kids who chew it are three and a half times more likely to start smoking cigarettes. Both R.J. Reynolds and Phillip Morris have introduced snus products, a less messy version of what chewing tobacco used to look like. These small, contained mesh packages are placed just under the upper lip, making it more difficult to detect and eliminate the need for a spitting cup. It really sounds pleasant, doesn't it?

While the research is not definitive, many claim that smokeless tobacco is less harmful than smoking. A recent 60 Minutes investigation on the use of smokeless tobacco claims that because tobacco manufacturers are not allowed to advertise that it is any safer than cigarettes, their ads focus on smokeless tobacco as a way to get around smoking bans, using smokeless tobacco in the sub-

way or at work.

I think that smokeless tobacco is a serious health hazard. I think we have to do more to prevent young people from forming these early addictions, and I look forward to hearing from our witnesses today, most especially from former Major League Baseball player Joe Garagiola, Sr.—it is really an honor to have you here and to see you, I am a great fan of yours—and to understand how our Nation's role models can set good, healthy examples for the younger generation who look up to them.

Thank you, Mr. Chairman, and I look forward to the testimony.

Mr. Pallone. Thank you.

Next is the gentleman from Indiana, Mr. Buyer.

OPENING STATEMENT OF HON. STEVE BUYER, A REPRESENT-ATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. BUYER. Thank you very much.

First of all, I would like to express my disappointment that no one from the Center for Tobacco Products is here to testify today,

and now that the Center is up and running, we do not have a single witness from what is to be the premier tobacco regulator in our country, so I am very disappointed, and I have a sense that the

Center has been deliberately disregarded in this hearing.

I continue to remain very interested in the issue of smoking cessation in country. Chairman Waxman and I feverishly debated this matter last year and I continue to follow the science behind smoking cessation with hopes that we can share valuable information with 45 million Americans who continue to smoke today despite strong public health campaigns that have been in operation for 40 years. We know that today over 70 percent of the tobacco users want to give up smoking, and treatments for the diseases related to tobacco are costly for our country. However, according to the Surgeon General's report in 2008, of the 45 percent of smokers who reported trying to quit in 2008, only 4 to 7 percent were successful and I believe that that is failure, and what is really disappointing is, is that the bill that was passed locks America into a system of failure. Americans have no access to information about the alternative methods of smoking cessation. For decades we have left them with the understanding that they must either quit smoking or die. However, this is not the only option for them, and there is a vast schism in the public health community that is crying out for the FDA and government officials to acknowledge the scientific research which continues to show that individuals throughout the world are finding tremendous success through harm-reduction strategies yet we continue to ignore harm-reduction strategies with regard to smoking. Oh, we will apply them to everything else in life but not to smoking, and I think that is pretty ridiculous. If we continue to employ harm-reduction strategies and give Americans this information showing the respective risks of tobacco products ranging from cigars and cigarettes to smokeless products and eventually pharmaceutical smoking products and complete cessation, we can give Americans who cannot or will not quit smoking new options to obtain the nicotine that they are dependent on or from products that are up to 99 percent less hazardous than cigarettes in terms of risk of tobacco-related illness. We must acknowledge the growing public health community that is acknowledging the differential risks between cigarettes and non-burning tobacco products including almost 80 peer-reviewed scientific and medical publications over the last 25 years of which four of them, Mr. Chairman, I am going to ask be submitted for the record.

The FDA stated on its Web site that it will perform its duties by using the best available science to guide the development and implementation of effective public health strategies to reduce the burden of illness and death caused by tobacco products. In carrying out its responsibilities to implement the bill we passed last year, while neither the FDA nor the Center for Tobacco Products are here to testify, I look forward to asking the CDC and NCI about their initiatives to incorporate the latest science into our Nation's tobacco control programs so that we can most effectively reduce

death and disease attributed to tobacco. I yield back.

Mr. PALLONE. Thank you, Mr. Buyer.

Next is the gentleman from New York, a big fan of Major League Baseball, from what I remember, Mr. Engel.

OPENING STATEMENT OF HON. ELIOT L. ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. ENGEL. Well, thank you very much, Mr. Chairman, for having this important hearing today to examine the prevalence in use of smokeless tobacco products, the health effects from use of these products and the correlation between smokeless tobacco use by

youth and Major League Baseball players.

It is fitting, Mr. Chairman, that we hold this hearing in April as our Nation has once again embraced the start of a baseball season. I represent the Bronx. I am from the Bronx, and I grew up less than half a mile from Yankee Stadium, and I love the Mets as well, so know how much joy the game can bring for so many families including my own three children. I can't even count how many games I have brought them to, and thank you, Mr. Chairman, for remembering that I am a big baseball fan. And these players rightly or wrongly are someone kids are fascinated with for their athleticism and accomplishments for the best of the best in baseball. Kids are like sponges soaking up everything around them, and whether or not it seems subtle, they pick up on one of the more unfortunate aspects of baseball, which is the prevalent use of smokeless tobacco. Today we have reports that up to a third of Major League players report using this highly addictive drug. Smokeless tobacco puts people at risk for oral cancer, gum disease, heart attacks, cardiovascular disease and cancer. It also causes leukoplakia, a disease of the mouth characterized by white patches and oral lesions.

I want to commend Major League Baseball for trying to proactively help our players and in turn the kids that look up to them through their efforts. The 1993 minor league tobacco policy has banned the use and possession of all tobacco products by club personnel and by players in minor league ballparks and during team travel as well. Major League Baseball established the National Spit Tobacco Education Program, called NSTEP, to curb the use of smokeless tobacco products through public service announcements featuring popular players and education and treatment programs for players, but there is a major gap in MLB. While personnel are barred from smoking with a uniform in view of spectators, they can still chew tobacco. MLB has said that this policy is one that the players association has sought to protect in collective bargaining. I am concerned that the players association continues to contend in their written testimony today that baseball players should not be prohibited from using substances that are legal and available to the general public. Mr. Prouty has even said that it is impossible for most fans to tell if players are using smokeless tobacco while playing baseball or in the dugout. I have to say I am disappointed in this response. There have been well documented instances of players on TV being clearly shown to be using smokeless tobacco. In fact, in one World Series game in 2004, at least 9 minutes of such footage was shown, so kids do see it. And secondly, while smokeless tobacco may be legal, there is a difference between players who want to use it in the privacy of their own homes and when they are on TV being paid very generous salaries to provide entertainment to millions of families each night. Every workplace has rules about what their employees can and

cannot do. Such is a matter of respect for the institution of Congress. We have to wear suits and ties or other appropriate attire when on the floor of the house. So therefore, it seems quite fair and reasonable that players abstain from using smokeless tobacco on the field, and I urge the players association to continue to consider these facts.

I want to welcome Joe Garagiola, who is one of my personal heroes, and the other people testifying today, and I thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Engel.

Next is the gentleman from Georgia, Mr. Gingrey.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENT-ATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. GINGREY. Mr. Chairman, thank you.

According to a 2007 CDC study, 20 percent of high school students smoke cigarettes and 8 percent of them use smokeless tobacco. While smokeless tobacco may not be as prevalent among teenagers as cigarettes, it can be no less damaging to their health. All forms of oral tobacco have chemicals known to cause cancer of the mouth, pancreas and esophagus. Oral and smokeless tobacco also cause many other health problems such as gum disease, destruction of bone sockets around the teeth and eventually tooth loss.

All of us here today have experienced the pain and the loss that comes with the onset of cancer. The mother of one of my staff, her name is Mrs. Margaret Horn, was diagnosed with leukemia a year and a half ago. There are many like Margaret in communities and cities across this country that will face cancer in their lifetime. It is a deadly disease and one for which a cure is long, long overdue. It is with this thought in mind that I want to thank Chairman Pallone for his interest in this subject. Even one death from cancer is one too many.

Today we understand the impact that advertising and pictures can have on our youth. Early movie stars of the 20th century made smoking so fashionable. I even remember seeing ads in magazines like Look and Life where there would be physicians in their white coats and the stethoscope in their pocket. They kept in the pocket back in those days. They didn't drape it around their neck. But they would have a cigarette in their hand. It was just amazing, and I am sure all of you have seen those ads.

And of course, there are some baseball players who will always in part be remembered for the amount of tobacco that they could stuff into their cheek. Like anyone up on stage, heroes can be memorable for the big things and for the little things they do. With any impressionable child comes a chance that they could emulate their heroes. To deny it is to deny the importance that our heroes have to us as adults looking back. The number of people on both sides of the dais of the committee members paying tribute to Joe Garagiola, I do the same. I remember when I was a kid growing up, and I loved catchers. I never played catcher but I loved to follow the career of Joe Garagiola and Clint Courtney and of course Yogi Berra. So, you know, we all look back on our heroes and look up to them. If smokeless tobacco was not something readily associ-

ated with baseball players, I don't believe that bubble gum today would be sold in packages that resemble these tobacco pouches. When I was a kid, that is not how you got bubble gum. So in short, there is an obvious correlation between the two.

I do want to make one point in light of all the testimony that we are going to hear today. I do not doubt that children may look up to baseball players or movie stars. However, I think it is fair to say that parents can and should be their greatest heroes. There will be many things in life, many choices that are our children will face, many influences they will have to weigh. It is the parents who have the greatest opportunity and ability to educate our children about things not only tobacco but alcohol and drugs and a lot of bad behavior. With this thought in mind, Mr. Chairman, I would like to encourage this committee not to forget the role that an informed and engaged parent can have on the health of their children.

I look forward to hearing from both panels of witnesses. Thank you so much for being with us today. I yield back.

Mr. PALLONE. Thank you.

The gentlewoman from Colorado, Ms. DeGette.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman.

I have to say, I completely agree with the gentleman from Georgia about the role of parents, and that also is my view, that parents need to have a strong oversight over their kids. But also in addition to that, I think the gentleman will agree with me on this too. Study after study has shown that advertising influences for tobacco and tobacco products are particularly strong among minors, and in the past in the many hearings that this committee has had, we have seen the effects of advertising by tobacco companies on minors. In fact, in my home State of Colorado, the tobacco industry is spending \$171 million per year, and they will say that they are not targeting that at minors, but as we have seen in many hearings, much of that advertising is accepted by minors.

I will also say, being the parent of two young daughters, teenage and young adults, I see that we have to revisit these issues with every generation. My older daughter, who is in college now, tells me that she is seeing many of her friends who are highly educated, intelligent young people smoking and using smokeless tobacco because they think it is cool, and so we have to revisit these issues generation after generation and we have to make sure that the people who these kids look up to are not using tobacco products with

the assumption that they are OK for the kids.

I am especially concerned about the smokeless tobacco because in places like Colorado, kids now are told from an early age that smoking can kill them, but in many areas the kids turn toward smokeless tobacco because they are not getting that same message, and so I really look forward to working with Major League Baseball and with all of my colleagues on this committee to make sure those same messages are getting out to kids and to make sure that our

role models for these kids including baseball players are also giving that consistent message.

My younger daughter, who is 16, is the biggest Colorado Rockies fan who exists. Her whole room is filled with posters of these players, and it is pretty cute to me because she is a girl, but she loves these players, she looks up to them as her peers and her friends and she goes to every game, so I want to make sure she gets the right messages from them, just like I want to make sure she gets the right messages from anybody else who is appealing to the teen market.

Mr. PALLONE. Thank you.

The gentlewoman from Tennessee, Ms. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. Blackburn. Thank you, Mr. Chairman.

Welcome to all of our witnesses today. We are pleased that you are here and we appreciate the time that you have taken to pre-

pare your testimony and be with us.

Mr. Chairman, I will have to tell you, I do find it a bit perplexing that we are here once again to discuss youth tobacco usage when I have offered my bill, H.R. 1423, as an amendment in this committee not only this Congress but also last Congress to address this very issue, and unfortunately that request has fallen on deaf ears but we have had it here in committee and in subcommittee and looked at this during the markups in the 110th and the 111th Congress. H.R. 1432 is a good government piece which focuses on strengthening existing programs to prevent illegal tobacco use. The bill strengthens the existing work that States and localities are doing to reduce underage access to and use of tobacco products through the evolution of SINAR, a current successful and effective program to lower teen smoking. The legislation takes the next step in the evolution towards protecting youth and informing the public regarding tobacco products. Mr. Shimkus mentioned the use of the MSA funds, and it would have required States to use at least 10 percent of those MSA funds on smoking cession and prevention programs. In addition, it would require the States to enforce their laws prohibiting the sale of tobacco products to minors or risk losing 40 percent of their federal subsidies. So when you say, those of you on the other side of the aisle say you are not sure about what to do, let me tell you, we have some things that have been offered and we should be doing them, and I do feel that if the Democrat leadership was serious about reducing youth tobacco usage, surely there would have been thoughtful debate given to that legislation.

But yet we are going to blame Major League Baseball for the ills of youth smokeless tobacco usage so let us be clear. If the MLB wants to change its policy on smokeless tobacco, an agreement will be reached between the MLB and the MLB players association. As the former president of the Middle, Tennessee, Lung Association, and as a grandmother with a 23-month-old who gets up every single morning and says go outside, play baseball, it is his favorite thing to do, I am very fully aware, I am fully aware of the risk of

youth usage of tobacco. I just find it a little bit of grandstanding that you would pass not only in the 111th Congress but also in the 110th Congress to take action and at a time when we should be dealing with a budget that the Democrat leadership does not want to deal with and when we should be looking at the problems that have already been found with the health care that passed, we are here once again addressing this issue when the solution is clearly in front of you. I yield back.

Mr. PALLONE. Next is the gentlewoman from California, our vice

chair, Ms. Capps.
Mrs. Capps. Thank you, Chairman Pallone, for holding this extremely important hearing. I wish to introduce for the record two important statements from our non-governmental organizations, one being Legacy and the other, the American Association for Cancer Research, in support of this hearing.

[The information appears at the conclusion of the hearing.]

Mr. Pallone. Without objection, so ordered.

OPENING STATEMENT OF HON. LOIS CAPPS, A REPRESENTA-TIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mrs. CAPPS. It is common knowledge that tobacco is unhealthy, dangerous and deadly. While we as a Nation have taken great steps to reduce tobacco use, especially cigarette smoking, we should all be alarmed by recent studies showing an increase in smokeless tobacco use among young people. In my field of public health, I am especially concerned that smokeless tobacco products are somehow seen as a safe alternative to cigarettes. We know conclusively that tobacco is an addictive substance in any of its forms. It causes numerous types of cancer, gum disease, oral lesions and increases one's risk of cardiovascular disease. What is worse is that some of these health repercussions can occur within just a few years of use.

Tobacco companies have a history of targeting their marketing campaigns to children and youth, encouraging them to start using their products at an early age. One particularly effective strategy was to get celebrity baseball players to endorse and use their products both on and off the field. We continue to deal with the nega-

tive repercussions of this today.

I commend the work that baseball has done to curb the use of smokeless tobacco. I salute you for that. In particular, the ban on its use in the minor leagues was a bold step to improve the health of both their players and the public. Despite these efforts, Major League Baseball continues to be a venue where smokeless tobacco usage is glamorized. At best, it is free advertising for the tobacco industry. At worse, it is putting the lives of America's children at

On a personal note, I have seen how my own grandchildren look up to athletes with such admiration. Children and adolescents watch these games to see their heroes compete. They try to mimic their throws and their swings. What else will they copy? While I sincerely hope that children who look up to baseball players can learn to filter out the negative messages they are receiving about smokeless tobacco use, you know, they really shouldn't have to do that. So I look forward to hearing from our witnesses today and appreciate the fact that you are here, and I yield back my time.

Mr. PALLONE. Thank you, Ms. Capps. The gentleman from Texas, our ranking member, Mr. Barton.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Chairman Pallone.

There is a famous poem about Casey at the bat that starts out, and I am trying to quote it from memory, so if I miss it, I apologize to those who know it by heart. But it says, "Somewhere birds are singing, somewhere people shout but there is no joy in Mudville, mighty Casey has struck out." This is a hearing that appears to have struck before we have even started it, Mr. Chairman, not that I don't like baseball, I love baseball. I remember when Joe Garagiola was actually a catcher for the Pittsburgh Pirates. That shows how far back I go. We are glad to have him here. I am not a big fan of tobacco. I have never smoked a tobacco cigarette. I have never used smokeless tobacco. I don't allow smoking in my office. That has been a policy since I got elected in 1985. So I am not an apologist for the tobacco industry. I don't accept and never have political action contributions from tobacco companies. But I don't see the need, Mr. Chairman, on this particular hearing the way it is structured. We have passed a law regulating tobacco products. I didn't support that law. Under that, the FDA has issued rules prohibiting the marketing of tobacco products to people under the age of 18. Their rule has been put on their Web site. It appears to me to be pretty explicit and fairly exhaustive in its attempt to prevent tobacco products getting to our youth. There may be a few Major League Baseball players that are under the age of 18. I am not aware of any but I guess it is technically possible. If a Major Leaguer wants to use a tobacco product, he still has that right under our Constitution to do so. If that product happens to be smokeless tobacco, he has the right to use it, and so far as I know, there is not a prohibition against a Major League Baseball player being a sponsor or somehow a spokesperson or being used in an advertising campaign for that product. Again, I am not defending the product, but even under the new law, it is a legal product.

So we are going to have a hearing today, Mr. Chairman, where we appear to be trying to intimidate Major League Baseball into prohibiting or discouraging their players from engaging in either the use of these products or serving as spokespersons and in some sort of advertising situation for those products. I think that is a misuse of the subcommittee's time, Mr. Chairman. I think time would be better spent if we began to investigate and oversee this recent mammoth 3,000-page health bill that is now the law of the land. I was given yesterday a draft, a 55-page draft of the mandates and the timelines in that bill that are now law. There are many mandates that become effective date of enactment, which is March 23, 2010, that are already not being honored by the Obama Administration. I think our time would be better spent, Mr. Chairman, if we began immediately to see what the pluses and minuses are of the new health care law and spent less time appearing to do a grandstand hearing simply because Opening Day was a couple weeks ago and people are beginning to focus on the diamond and what activities are going on in Major League Baseball.

I do thank the witnesses for appearing. I know you are here sincerely to express your position and that there are issues to be addressed. I don't think it should the subject of a Congressional hearing at this point in time.

With that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Barton follows:]

Opening Statement
Honorable Ranking Member Joe Barton
"Smokeless Tobacco: Impact on the Health of our Nation's
Youth and Use in Major League Baseball"
Subcommittee on Health
Wednesday April 14, 2009

Mr. Chairman, somewhere there is laughter, and somewhere children shout. But here today in Rayburn, the committee has struck out.

I love baseball. It IS the great American pastime. I don't play much anymore, but I don't use tobacco and I doubt my son will ever feel the need to use tobacco to be a ballplayer.

I do wonder why we are having this hearing. Kids are informed directly by their parents and teachers, but they also draw lessons from all sorts of media, and they follow sports other than baseball. Yet it appears that the Majority

has concluded that it is Major League Baseball that molds our children into the adults they will become.

The baseball season has just started and the false hopes of fans in towns like Oakland, Los Angeles and Seattle will be high until they travel to, oh, let's just say Arlington, Texas. So this is the moment to have Major League Baseball testify because it constitutes a grand opportunity for us to get some press while spring is in the air and Casey is just coming up to bat. But I am concerned that America may think we are sneaking off the to ballgame. I went home during recess and in multiple town hall meetings, not a single person asked me a single question about baseball, much less about ballplayers and tobacco.

I did, however, receive a cascade of questions about the effects of the 3000-page health care bill on the lives of

Americans. People want to know if their taxes will increase. People want to know whether the bill will hinder the creation of new jobs. People want to know whether they would lose their current health coverage. People want to know what insurance qualifies for the individual mandate.

It seems bizarre that we can probe the health concerns of ballplayers chewing tobacco, but only managed a single hearing on a one-day-old, 3000-page health bill that will touch the lives and pocketbooks of every living American, and with witnesses who weren't even expected to discuss its substance

I believe it is fair to say that this hearing is a distraction. Seniors ask me how their Medicare plans will be changed by the \$500 billion in cuts that will be used to pay for a new entitlement. We can't know for sure because

this Committee has not held a single hearing on how these cuts will affect seniors and the Medicare program. Seniors ask me if their Medicare Part D premiums will increase or if their access to Medicare Advantage plans will be affected. This Committee has not held a single hearing on the issue, so who knows?

Today, physicians are experiencing a 21 percent cut in their Medicare reimbursement rates and face future cuts of 5 percent annually. Because the Democrats relied on budget tricks to pass their health care bill, they refused to put a long-term fix to this problem in their bill, thereby *pretending* to reduce the deficit. Rather than solve the problem, Democrats enact a series of one-month fixes that provide no certainty to doctors treating patients around the country. This approach can only be generously described

as irresponsible. Of course, this Committee has yet to hold a hearing on the issue in the last two congresses.

Turning to the substance of today's hearing, according to a recent report from the Campaign for Tobacco Free Kids, only one state currently funds a tobacco prevention program at the level recommended by the U.S. Centers for Disease Control and Prevention (CDC). Only nine other states fund tobacco prevention at even half the CDC-recommended level, while 31 states provides less than a quarter of the recommended funding.

A peer-reviewed article from the July 2007 Preventing Chronic Disease found "Significant reductions in smoking prevalence among Washington residents following the implementation of a comprehensive tobacco control program funded at a level near that recommended by the Centers for Disease Control and Prevention indicate that tobacco control programs are an effective investment for states committed to improving public health." We already know what works. But it seems we are opting to ignore that report so we can hold a media-grabbing hearing about Major League Baseball, instead.

I will end by thanking the CDC for being here today. We also have legislation before the Committee related to the 9/11 health program that affects your Agency. In fact, that bill has been marked up in the Health Subcommittee. Unfortunately, we held a hearing last year, but CDC was not asked to testify. Hopefully, before we move that legislation through Full Committee, we will have your Agency testify. I would hope that the Chairman would be willing to make that commitment.

Thank you, I yield back the balance of my time.

Mr. PALLONE. The gentlewoman from the Virgin Islands, Ms. Christensen.

OPENING STATEMENT OF HON. DONNA M. CHRISTENSEN, A REPRESENTATIVE IN CONGRESS FROM THE VIRGIN ISLANDS

Mrs. Christensen. Thank you, Mr. Chairman.

When we passed the Family Smoking Prevention and Tobacco Act, we did so to control and hopefully reduce all tobacco use, so I want to thank you, Chairman Pallone and Ranking Member Shimkus, for holding this hearing because we are seeing companies trying to redirect their marketing to the smokeless tobacco market and it is important to remind everyone that smokeless tobacco is also addicting and has harmful effects such as oral and throat cancer and increased risk for esophageal, stomach and pancreatic cancers as well as heart disease and stroke. So smokeless tobacco is by no means a safe substitute for cigarettes. Therefore, the increasing use of smokeless tobacco among anyone but especially today's youth is quite troubling to me as a physician, a mother and a grandmother of a 3-year-old who is now in tee ball.

The history of smokeless tobacco use in Major League Baseball only exacerbates the problem in today's youth because of the influence that athletes, celebrities and entertainers have on them. However cool, exciting or glamorous these athletes or celebrities may seem, there is nothing cool, exciting or glamorous about the harmful effects caused by using smokeless tobacco that could impair or cut short the potential of a young person before they even get the

chance to experience all that life has to offer.

The bill we passed and the President signed will restrict marketing and advertising of tobacco products near schools and playgrounds beginning this summer as well as implement other limitations, but that is not enough. We do appreciate the actions that the minor leagues have taken and look forward to stronger action from Major League Baseball and to working together around this Act and any additional legislation or initiatives that will work to reduce and prevent the use of smokeless tobacco and all tobacco in today's youth.

We appreciate our witnesses being here. We would like to welcome also especially Joe Garagiola and we look forward to the testimonies. Thank you. I yield back.

Mr. PALLONE. Thank you.

The gentleman from Utah, Mr. Matheson.

Mr. MATHESON. Thanks, Mr. Chairman. I will waive my opening statement.

Mr. PALLONE. The gentlewoman from Illinois, Ms. Schakowsky.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. Schakowsky. First of all, Mr. Chairman, I want to thank you for holding this hearing. It is never a waste of time for us to focus on health risks that are posed to our children and to have a thorough discussion over what may be done either within this Congress or outside of in order to make sure that our children are protected.

We know that on March 31st President Obama signed the PACT Act into law, and this new law is a huge step forward in our fight against the underage use of tobacco products and was built on decades of advocacy and public outreach, and I applaud this victory but I know that we have much work ahead. Big Tobacco is still finding its way into the lives of our youth. I think everyone in this room knows that chewing tobacco is just as dangerous as lighting a cigarette, and we have heard over and over what those risks are, but we have also started to see a resurgence in the use of these products among young people, particularly among young men, and prevention is an ongoing process, as my colleague, Congresswoman DeGette, said. Every generation we always have to keep repeating

As I was preparing for this hearing, one of my wonderful interns, Michael Cottler, told me stories about his college baseball team. Half of his team used tobacco products. Most of them would chew but not smoke, and according to him, the players chewed during games, not off the field. His experience tells me we still have work to do and that a big chunk of the responsibility to stop use of tobacco products by underage kids comes from the role models that they look up to. And every time I watch a baseball player spit before stepping up to the bat, I know there are young ballplayers who dream of becoming pros who see those images too.

According to the Harvard study of public health, just one World Series game in 2004 had over 9 minutes of free advertising for the tobacco industry because of shots of players chomping on chew. I mean, you know, sometimes it surprises me that this is looked at as attractive in any way but apparently to young men, it does look

very cool and authentic.

Smokeless tobacco is not a healthier substitute for cigarettes. It destroys lives and kills just as effectively as its smoked counterpart. There has been an incredible grassroots effort to educate the public about the dangers of smoking and we have seen a significant reduction in underage smoking because of it. Without that same commitment, I worry that young people like my intern's baseball team will see chewing as an OK substitute for cigarettes.

I applaud the minor league tobacco policy which has taken smokeless tobacco out of the clubhouses and ball fields of the minor leagues. We are going to need that same type of aggressive action at the major league level if we are going to get tobacco products out of the game, and I yield back.

Mr. PALLONE. Thank you.

The gentleman from Texas, Mr. Green.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Green. Thank you, Mr. Chairman, for holding the hearing on smokeless tobacco and the impact on our Nation's children and

use in Major League Baseball.

Each year millions of teenagers use smokeless tobacco. According to the CDC, 13.4 percent of U.S. high school boys and 2.3 percent of high school girls currently use smokeless tobacco products. Youth prevalence data from the Centers for Disease Control also shows that while cigarette smoking has declined substantially in

the last 10 years, smokeless tobacco use has decreased only slightly over that period. The CDC found that among high school boys, usage rates of smokeless tobacco increased by 22 percent between 2003 and 2007. There is a perception that smokeless tobacco is a safe product and we should be clear that studies have found that smokeless tobacco can contain as many as 28 different carcinogens and smokeless tobacco causes oral cancer, gum disease, increased risk of heart attack, cardiovascular disease and nicotine addiction. The World Health Organization's International Agency for Research on Cancer concluded that smokeless tobacco users have an 80 percent higher risk of developing oral cancer and 60 percent higher risk of developing pancreatic and esophageal cancer. Smokeless tobacco can be an alternative to smoking cigarettes and may be perceived as safer than smoking cigarettes but there are still

significant health risks associated with smokeless tobacco.

Today we are discussing the use of smokeless tobacco in Major League Baseball and how that impacts our youth. Like my colleagues, there is nothing more American than baseball. I am a fan of the Houston Astros. I actually worked there. I had the ideal job for a 7th grader. I could sell soda water and earn \$10 a night and see all the baseball I wanted. In fact, I skipped school to be able to go to Opening Day when we had the Colt 45, so I remember it very well. But we still have to provide the leadership from the players. Major League Baseball has banned cigarette use by major league players in uniform and in view of the public, has been banned for over 3 decades. However, there are no restrictions on the use of smokeless tobacco. Steps have been taken to restrict smokeless tobacco use by players in uniform in minor league baseball but these measures have not been in place in the major leagues. We do know that in 2003 approximately 36 percent of the baseball players in the league reported using smokeless tobacco. These players are idolized by our children and seen using smokeless tobacco which certainly we do not want to encourage our youth to begin using a harmful product because they see a sports hero using it.

I look forward to the testimony of our witnesses, Mr. Chairman, and I yield back my time.

Mr. PALLONE. Thank you, Mr. Green.

Next is the gentleman from Georgia, Mr. Barrow.

Mr. BARROW. I thank the chairman. I will waive an opening.

Mr. PALLONE. Thank you.

I think that everyone has had an opportunity to—

Mr. Shimkus. Mr. Chairman?

Mr. Pallone. Yes?

Mr. Shimkus. I ask unanimous consent that my statement be submitted into the record. Would that go for everyone?

Mr. PALLONE. Yes. Without objection, it ordered that every member's statement in full will be submitted for the record.

Mr. Shimkus. Thank you.

Mr. PALLONE. We are now going to turn to our witnesses, our first panel. I want to welcome them. Let me introduce the two of you. First is Dr. Terry Pechacek, who is associate director for science for the Office on Smoking and Health within the Centers for Disease Control and Prevention. And on my right is Dr. Debo-

rah Winn, who is deputy director for the Division of Cancer Control and Population Sciences with the National Cancer Institute. Thank you both for being here. You know the drill. You have 5-minute openings that become part of the record, and of course, if you like, you may in the discretion of the committee submit additional statements in writing for inclusion in the record.

We will start with Dr. Pechacek.

STATEMENTS OF TERRY PECHACEK, PH.D., ASSOCIATE DIREC-TOR FOR SCIENCE, OFFICE ON SMOKING AND HEALTH, CEN-TERS FOR DISEASE CONTROL AND PREVENTION: AND DEBO-RAH WINN, PH.D., DEPUTY DIRECTOR OF THE DIVISION OF CANCER CONTROL AND POPULATION SCIENCES, NATIONAL **CANCER INSTITUTE**

STATEMENT OF TERRY PECHACEK

Mr. PECHACEK. Mr. Chairman, Ranking Member and distinguished members of the subcommittee, thank you for the opportunity to participate in this hearing. My name is Dr. Terry Pechacek and I am the associate director for science in the Office of Smoking and Health at the Centers for Disease Control and Prevention. Today I will provide an overview of smokeless tobacco including health effects, trends and product use, and use of smokeless products and their marketing.

I want to begin by emphasizing a very important point. There is no safe form of tobacco use. Use of any tobacco product is hazardous to health. The only proven way to reduce the staggering toll that tobacco use takes on our society is to prevent people from ever starting to use tobacco and to help those who already use these

products to guit as early in life as possible.

What is smokeless tobacco? Smokeless tobacco products come in two forms: chewing tobacco and snuff, or ground tobacco. In recent years, a new generation of smokeless tobacco products has entered the U.S. market. They include snus, a form of moist snuff, and dissolvable products such as lozenges, sticks and strips. The questions in national surveys that I will cite in this testimony generally ask respondents about the use of smokeless tobacco products without disaggregating information by specific product types.

The scientific evidence clearly shows that using smokeless tobacco products is hazardous to health. They contain at least 28 carcinogens and are known to cause oral, pancreatic and esophageal cancer. Some studies have also linked smokeless tobacco use to fatal heart attacks and certain adverse productive outcomes during pregnancy. Like cigarettes, smokeless tobacco contains nicotine and is highly addictive. As individuals use smokeless tobacco over time, they typically change products they use to get more nicotine. In doing so, they may be increasing their exposure to carcinogens and other toxic agents.

The National Survey on Drug Use and Health, or NSDUH, which is conducted by the Health and Human Services' Substance Abuse and Mental Health Service Administration, indicates that about 3.5 percent of persons in this country age 12 and older, or approximately 7.8 million persons, used smokeless tobacco in the past month. Men are more likely than women to use smokeless prod-

ucts. In fact, the highest prevalence of smokeless tobacco use in recent years has been among young adult men. Therefore, this testimony will focus on recent trends related to this population. The NSDUH survey reported a significant increase in smokeless tobacco use among persons 12 years and older from 3 percent in 2004 to 3.5 percent in 2008. During these years, patterns of use among persons 26 and older have remained relatively stable at about 3 percent. Patterns of use among adolescent girls have also remained stable at a very low level. The observed increase primary comes from an increase among men 18 to 25 years of age, especially in two demographic groups. Among non-Hispanic white men, rates increased from 13.6 percent in 2003 to 15.4 percent in 2008. Among Hispanic men age 18 to 25, rates of smokeless tobacco use increased from 1.9 percent to 3.4 percent during that same time. Recent data from Monitoring the Future also confirms an increase among young males with the rate increasing from 15.8 percent in 12th-grade boys in 2008 up from 11 percent in 2007. Data from CDC's 2009 youth risk behavior survey, which will be released this summer, also is showing significant increase in smokeless tobacco use since 2003 among both male high school students overall and non-Hispanic white high school students.

As with smoking, most smokeless tobacco use begins during adolescence and young adulthood. Data from NSDUH shows that in 2002, about 950,000 Americans 12 years and older used smokeless tobacco for the first time. By 2008, that number had increased to 1.4 million. Almost half of those first-time users were under 18 and almost three-fourths were male. Traditionally, cigarette smokers and smokeless tobacco users have been fairly distinct groups. However, several national surveys show that a large proportion of smokeless tobacco users are also smoking cigarettes. This pattern is most common among adolescents and young adults than among older Americans. In fact, the data indicates that two-thirds of males between 18 and 25 who use smokeless tobacco also smoke cigarettes. These trends need to be placed in the changing context of tobacco use in the United States including lower smoking rates, increased restrictions in smoking in public and increased social acceptability of smoking.

Mr. Chairman, am I over my limit?

Mr. PALLONE. You are, but you can wrap up if you like.

Mr. Pechacek. So the marketplace has been changing with the promotion of tobacco products increasing from 200 million in 2005 to 300 million in 2006, and particular concern is that many of these smokeless products are being marketed in ways to satisfy and sustain their nicotine addictions when they are settings that do not

allow smoking.

So what is the public health harm? This dual use raises potential concerns. More than half of adolescents and young adults who are using smokeless tobacco also are smoking cigarettes. I have submitted my written testimony, which provides greater details on these important issues, but it is important to emphasize that recent increases in smokeless tobacco use by adolescent boys and young men as well as increasing dual use of cigarettes and smokeless tobacco are reasons for serious concern. Together these may portend a leveling off or even reversal in the decline of smoking

and the perpetuation of nicotine dependence including high levels of tobacco-related disease and death in this country.

Thank you for the opportunity to participate in this hearing and I would be happy to accept questions.

[The prepared statement of Mr. Pechacek follows:]



Testimony
Before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

Hearing entitled, "Smokeless Tobacco: Impact on the Health of our Nation's Youth and Use in Major League Baseball"

Statement of
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Promotion
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U.S. Department of Health and Human Services



For Release on Delivery Expected at 10:00 a.m. Wednesday, April 14, 2010 Mr. Chairman, Ranking Member, and distinguished members of the Subcommittee, thank you for the opportunity to participate in this hearing. My name is Dr. Terry Pechacek, and I am the Associate Director for Science of the Office on Smoking and Health at the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (HHS). I will provide a brief overview of the health effects of smokeless tobacco products, recent trends in the use of these products, and the evolving forms in which these products are available and marketed.

No Safe Form of Tobacco Use

I want to begin by emphasizing a very important point. There is NO safe form of tobacco use. The use of ANY tobacco product is hazardous to health. As a result, the only proven way to reduce the staggering toll that tobacco-related disease, death, and economic costs take on our society is to prevent people from ever starting to use tobacco products and to help those who already use these products to quit as early in their lives as possible.

What Is Smokeless Tobacco?

Smokeless tobacco products consist of tobacco or a tobacco blend that is chewed, placed in the oral cavity outside the gums, or inhaled or snorted through the nose, rather than smoked. Smokeless tobacco includes chewing tobacco and snuff. Chewing tobacco comes in several forms, including loose leaf, plug, twist, and roll. Snuff, which is finely ground tobacco, also comes in several forms, including moist, dry, or packaged in sachets.

Smokeless tobacco in the United States has traditionally been available in the form of chewing tobacco and dry snuff. During the 1980s, moist snuff became more widely available and more heavily marketed in the United States. The moist varieties, sold either in tins or in sachets, accounted for 97 percent of sales of snuff by weight in 2006. These moist snuff products were heavily advertised and promoted, including through ads featuring popular athletes that were likely to appeal to youth. Since the mid-1980s, smokeless tobacco use spread beyond its traditional base of older rural white men, and rates of smokeless tobacco use increased substantially, especially among young white males.

The questions in national surveys that we will be relying on to report on trends in smokeless tobacco use ask respondents about use of all smokeless tobacco products, without disaggregating this information by specific product types.

Smokeless Tobacco Use is Hazardous

The scientific evidence clearly shows that smokeless tobacco use is hazardous to health. At least 28 carcinogens have been identified in smokeless tobacco products. The International Agency for Research on Cancer (IARC) and HHS's National Toxicology Program have concluded that smokeless tobacco is a known human carcinogen. IARC has concluded that smokeless tobacco causes oral cancer, which can require disfiguring surgery, and pancreatic cancer, which is an especially deadly form of cancer. Smokeless tobacco use also has significant cardiovascular effects, and has been linked to fatal heart attacks. Some studies have also linked smokeless tobacco use to adverse reproductive outcomes during pregnancy, including preeclampsia, premature birth, and low birthweight. Finally, smokeless tobacco use is associated with leukoplakia (a precancerous lesion in the mouth), gum recession and disease of the gums, and tooth decay.

Smokeless Tobacco is Addictive

Like cigarettes and other tobacco products, smokeless tobacco products contain nicotine and are highly addictive. Like smoking, smokeless tobacco use can lead to nicotine dependence. As individuals continue to use smokeless tobacco products over time, they typically increase their intensity of use in order to increase their nicotine dose, in the process also increasing their exposure to the carcinogens in these products. Smokeless tobacco users also tend to switch brands to increase their nicotine intake as they become more experienced users, "graduating" from brands with lower nicotine levels to brands with higher levels.

Smokeless Tobacco Use by Demographic and Geographic Characteristics

Smokeless tobacco use is not spread evenly through the U.S. population. In 2009, data from the National Survey on Drug Use and Health (NSDUH), which is conducted by HHS's Substance Abuse and Mental Health Services Administration, provided an overview of recent patterns in

smokeless tobacco use in the United States. Combined 2002 to 2007 data indicated that an annual average of 3.2 percent of persons 12 years of age or older (an estimated 7.8 million persons) used smokeless tobacco in the past month. Certain demographic subgroups were more likely to use smokeless tobacco than others. Smokeless tobacco was more likely to be used among persons 18 to 25 years than among 12- to 17-year olds and those 26 years or older. Males were more likely than females to have used smokeless tobacco (6.2 vs. 0.4 percent). American Indians or Alaska Natives were more likely than persons in any other racial/ethnic category to have used smokeless tobacco.

Rates of smokeless tobacco use also varied geographically. Past month smokeless tobacco use was highest among persons who lived in completely rural and less urbanized counties in non-metropolitan areas and lowest among persons who lived in large metropolitan areas. Persons who lived in the South and Midwest were more likely than persons who lived in the West and Northeast to have used smokeless tobacco.

The highest prevalence of smokeless tobacco use in recent years has been observed among young adults, especially males. As with use of other tobacco products, NSDUH finds that smokeless tobacco initiation rates are highest among adolescents and young adults. These patterns have also been observed in other major national surveys. Therefore, this testimony will focus on recent trends in smokeless tobacco use among adolescents and young adults, especially males.

Recent Trends in Smokeless Tobacco Use

Three HHS national data sources provide the best available data on these trends: (1) NSDUH, which tracks tobacco use among persons 12 years and older; (2) Monitoring the Future, supported by the National Institute on Drug Abuse, which tracks tobacco use among 8th, 10th, and 12th grade students; and (3) CDC's Youth Risk Behavior Survey (YRBS), which tracks tobacco use among high school students.

NSDUH

NSDUH reported a significant increase in smokeless tobacco use among persons 12 years of age and older, from 3 percent in 2004 to 3.5 percent in 2008. During these years, patterns of use among persons 26 years of age and older have remained stable at around 3 percent. Patterns of use among adolescent girls and women have also remained stable at low levels. The observed increase appears to have arisen primarily from an increase among men 18 to 25 years of age, especially men in two specific demographic groups. Among non-Hispanic white men, rates increased significantly, from 13.6 percent in 2003 to 15.4 percent in 2008. Additionally, among Hispanic men aged 18 to 25 years of age, rates of past month smokeless tobacco use increased significantly, from 1.9 percent in 2003 to 3.4 percent in 2008.

Monitoring the Future

While the NSDUH does not show significant increases among 12- to 17-year-olds, recent data from Monitoring the Future survey suggest that smokeless tobacco use may be increasing among male students in the 8th, 10th, and 12th grades. For example, the prevalence of smokeless tobacco use in the past 30 days among male 8th grade students increased from 4.7 percent in 2007 to 6.3 percent in 2009. Also, among 12th grade boys, rates of use in the past 30 days increased overall, from 11.0 percent in 2006 to 15.8 percent to 2009.

Data on perceived risk of harm has been found to be a reliable leading indicator for emerging trends in adolescent cigarette smoking, marijuana use, and alcohol use. In 2009, perceptions of health risk from smokeless tobacco use declined among 8th, 10th, and 12th grade students, with the decline among 10th graders being significant. This decrease reversed a previous trend toward increased perceived risk.

YRBS

Data from the YRBS show similar trends. Smokeless tobacco use among female high school students remained unchanged and very low from 1995 to 2009, at about 2 percent. However, the most recent data indicate that rates of use among male high school students are increasing significantly. Unpublished analyses of trends in smokeless tobacco use within the YRBS, including data for 2009 which will be released by this summer, show recent significant increases

in smokeless tobacco use among males overall and among non-Hispanic whites overall from 2003 to 2009.

Most Smokeless Tobacco Users Initiate Use as Teens or Young Adults

As with smoking, most smokeless tobacco use begins during the adolescent and young adult years. Combined data from the NSDUH from 2002 to 2007 indicates that few adults 26 years or older reported initiating smokeless tobacco use. Data from the NSDUH also show that the number of Americans 12 years and older who used smokeless tobacco products for the first time in the past 12 months increased significantly, from 951,000 in 2002 to 1.4 million in 2008. Almost half of the first-time users in 2008 reported that they were younger than 18 when they first used smokeless tobacco products, and almost three-fourths of them were male. From 2004 to 2007, rates of smokeless tobacco use initiation increased significantly for males 12 to 17 and 18 to 25 years of age.

Many People Are Using Both Cigarettes and Smokeless Tobacco

Traditionally, cigarette smokers and smokeless tobacco users were fairly distinct groups.

However, in recent years there appears to be a trend toward dual use of these products. In looking at patterns of smokeless tobacco use across several national surveys, we find that a large proportion of smokeless tobacco users are also smoking cigarettes. This pattern of dual use is more common among adolescents and young adults than among older Americans.

An analysis of data from CDC's Behavioral Risk Factor Surveillance System from 10 states found a pattern of current smoking being associated with current use of another tobacco product, particularly smokeless tobacco, particularly for males 18 to 29 years of age. This analysis found that 26 percent of adult male smokers used another tobacco product, particularly smokeless tobacco. The proportion of adult smokers using other tobacco products was twice as high among 18- to 29-year-olds as among those 45 years and older.

In 2008 NSDUH data, 23.9 percent of persons 12 years and older were current cigarette smokers, and 3.5 percent used smokeless tobacco. Data reported from the NSDUH for the years 2002 to 2007 show that more than a third (38.8 percent) of all past-month smokeless tobacco users 12

years of age and older had also used cigarettes in the past month. Thus, the proportion of the overall population 12 years and older of both genders that reported using both products was about 1.4 percent.

However, patterns of use of both cigarettes and smokeless tobacco are not evenly distributed across the U.S. population. The proportion of past-month smokeless tobacco users who also used cigarettes in the past month increased to more than one half (52.8 percent) for persons 12 to 17 years and to two-thirds (66.9 percent) for persons 18 to 25 years of age. In 2008, 15.4 percent of non-Hispanic white men 18 to 25 years of age reported past month use of smokeless tobacco. Therefore, about 10 percent of this population of young men report past month use of both cigarettes and smokeless tobacco.

A recent, more detailed study examined this pattern of current smokers also using smokeless tobacco products using data from four national surveys. This study found that this association appears to be different for younger people than for older men who use smokeless products daily. This report found that the prevalence of daily smoking is very high among male students in middle school and high school who use smokeless tobacco. Additionally, these researchers found that non-daily, or "some day," users of moist snuff were more likely to be current smokers than any other group, and that this pattern was especially common among adolescents and young adult users of smokeless tobacco products.

The Changing Context of Tobacco Use in the United States

These patterns of use of smokeless tobacco products need to be placed within the changing context of tobacco use in the United States, including declining cigarette use, increasing smoking restrictions and decreasing social acceptability of smoking, and a change in the cigarette and smokeless tobacco industry and in marketing of these products.

Cigarette Use

Per capita cigarette consumption has decreased to its lowest point in over 60 years, and prevalence of current cigarette smoking among youth is at its lowest point since consistent public health tracking began in 1975.

Smoking Restrictions

Additionally, the number of Americans living under state or local laws banning smoking in workplaces and public places has increased significantly in recent years, reducing opportunities to smoke in many indoor settings.

The Changing Smokeless Tobacco Market

Researchers have pointed out that the smokeless tobacco product market has changed in recent years. In contrast to the situation that existed until 2006, when the smokeless tobacco market in the United States was represented primarily by companies that did not manufacture cigarettes, recent mergers and acquisitions have resulted in most of the production and sales of smokeless tobacco products concentrated in major cigarette manufacturing companies.

Smokeless Tobacco Is Available in a Number of New Forms

In recent years yet another new generation of smokeless tobacco products has entered the U.S. market. These products are now widely available in a number of new forms, including snus, a form of moist snuff, and "dissolvable" products such as lozenges, orbs, sticks, and strips. These novel smokeless products are available in a range of flavors, which research suggests makes products more attractive to youth. Like snus, these products may also be more appealing than traditional smokeless tobacco products to youth and females because they do not require spitting and can be used discreetly. In fact, young people can use these products in school or at home without their teachers or parents being aware that they are using tobacco. The appearance of these products, some of which look like breath mints, may also lead children and teens to perceive that they are harmless and may even disguise the fact that they contain tobacco.

Smokeless Tobacco Products Are Heavily Promoted

These moist snuff varieties and more recent variations of smokeless tobacco products are heavily advertised and promoted. Sales of the "moist snuff" category of smokeless tobacco products have increased annually since 1986, with the volume sold doubling over this period. Additionally, the advertising and promotional expenditures for this moist snuff category of smokeless tobacco products increased from \$210 million in 2005 to \$308 million in 2006, the most recent year for which these data have been reported. The timing of this increase is significant, since, as noted above, 2006 was the year when U.S. cigarette manufacturers began acquiring large smokeless tobacco concerns and marketing smokeless tobacco and snus named after leading cigarette brands. Researchers have suggested that test marketing of new smokeless tobacco product lines and other promotional campaigns have been concentrated in areas with large college student populations and in large urban areas with recently implemented smoke-free laws. There is also evidence that youth continue to be exposed to smokeless tobacco advertising in magazines, including sports-oriented magazines.

Professional athletes in certain sports, including baseball and rodeo, have traditionally had high levels of smokeless tobacco use. Athletes serve as role models for youth, and smokeless tobacco manufacturers have used advertising, images, and testimonials featuring athletes and sports to make smokeless tobacco products appear attractive to youth. Children and teens closely observe athletes' actions, including their use of tobacco products, and are influenced by what they see. Adolescents tend to mimic the behaviors of those they look up to and identify with, including baseball players and other athletes. Research suggests that male high school athletes may be at especially high risk for smokeless tobacco use.

Of particular concern, many of the new smokeless tobacco products are being marketed as a way for smokers to satisfy and sustain their nicotine addiction when they are in settings where they cannot smoke. In fact, ads for snus and other smokeless tobacco products explicitly promote these products as a way to use tobacco in workplaces, restaurants, sports arenas, airplanes, and other locations covered by smoke-free policies. Smokers may readily interpret these advertising

messages to mean that they can use smokeless tobacco products when they are in locations where they are not allowed to smoke while continuing to smoke in other locations. This may contribute to the trend towards dual use of cigarettes and smokeless tobacco discussed previously.

Potential Impact on Population Public Health

These emerging trends toward dual use of cigarettes and smokeless tobacco products among young adults raise some potentially serious concerns. First, public health researchers have suggested that many smokers who would otherwise have quit in response to the widespread implementation of smoke-free policies in workplaces and public places will continue smoking, since they can use smokeless tobacco products where smoking is prohibited and still continue to smoke where such bans are not in effect, thereby eradicating any beneficial behavioral modification that smoke-free policies would encourage. Second, the emerging trends suggest that the behavior pattern of using both cigarettes and smokeless tobacco products is changing among adolescents and young adults. This is of concern because long-term use of both of these products may pose health risks beyond those posed by smoking cigarettes alone. Even if dual use of cigarettes and smokeless tobacco products delay quitting rather than preventing it altogether, this would still pose a significant threat to public health. Duration of smoking is a key factor determining risk of adverse health effects, especially with regard to lung cancer and other forms of cancer. Even if concurrent use of smokeless tobacco leads smokers to smoke fewer cigarettes per day, the fact that they are continuing to smoke results in an increased risk for many diseases caused by smoking, particularly heart disease. The longer dual use of cigarettes and smokeless tobacco postpones complete cessation of smoking and tobacco use, the greater smokers' risk of developing lung cancer and other serious diseases.

Conclusion

Significant progress has been made toward ending the tobacco epidemic in the United States in recent decades. However, the data I have presented on the national trends in smokeless tobacco product use raise concerns that could potentially put this progress in jeopardy. Again, the bottom line is that there is NO safe form of tobacco use, including smokeless tobacco use. The best way

to protect one's health is to refrain from using ANY tobacco product or, if one is already a user, to quit ALL tobacco use. The recent increases in smokeless tobacco use by adolescent boys and young adult men and the increasing dual use of cigarettes and smokeless tobacco products may portend a leveling off or even a reversal in the decline in smoking, the perpetuation of nicotine dependence, and continuing high levels of tobacco-related disease and death in the country.

Thank you again for this opportunity. I would be happy to answer any questions.

Mr. PALLONE. Thank you, and thank you for being mindful of the time. I appreciate it.

Dr. Winn.

STATEMENT OF DEBORAH WINN

Ms. WINN. Thank you. Good morning. I am Deborah Winn, deputy director of the Division of Cancer Control and Population Sciences, National Cancer Institute, National Institutes of Health. Thank you, Chairman Pallone and distinguished members of the committee for the opportunity to be here to discuss smokeless to-bacco and its health consequences.

It is well established that the use of smokeless tobacco causes cancer of the mouth and throat, esophagus and pancreas. As far back as 1985, the Advisory Committee to the U.S. Surgeon General examined literature on health consequences associated with use of snuff and concluded that the evidence is strong that the use of snuff can cause cancer in humans. The evidence for causality is strongest for cancer of the oral cavity. The excess risk of cancer of the cheek and gums may reach nearly 50 fold in long-term snuff users. Global health authorities have also reached similar conclusions. The World Health Organization's International Agency for Research on Cancer, which I will call IARC, convenes expert panels to evaluate the world's scientific literature on environmental agents to determine whether those agents cause cancer. Those reports are considered to be highly authoritative and are used extensively worldwide to provide the scientific basis for public health action. This group has evaluated the carcinogenicity of smokeless tobacco three times over the past 25 years and I served as a member of all three panels. In 2009, IARC concluded that the use of smokeless tobacco causes cancer of the mouth, throat, esophagus and pancreas. These findings were based on international data from North America, Scandinavia and Asia, among other places. Using smokeless tobacco is associated with at least a fourfold increased risk of oral cancer.

Scientists have a fairly clear understanding of how smokeless tobacco causes cancer. It contains carcinogens, the most common of them being the tobacco-specific nitrosamines. Cancer may develop when metabolites of nitrosamines attach to DNA causing a genetic mutation. This mutation leads to other cellular disruptions and ultimately results in cancer. Nitrosamines are found in all tobacco products and are not safe at any level.

In addition to cancer, smokeless tobacco users are more likely than non-users to develop leukoplakia, or white patches in the mouth that can lead to cancer. Other changes in the lining of the mouth related to smokeless tobacco include wrinkling of the inner cheek and gums and color changes. In the 1980s, a national survey of teens found that more than 25 percent of children who used smokeless tobacco have these changes compared to less than 1 percent of children who did not use smokeless tobacco.

Cancer and leukoplakia are not the only adverse health effects linked to smokeless tobacco. It is also associated with gum disease, dental caries and reproductive effects such as decreased fetal growth, increased risk of preterm delivery and stillbirth. Other serious effects may include increase risk of heart attack and stroke.

A recent summary of data regarding this subject showed that smokeless tobacco increased the risk of fatal heart attack by 13 percent and death from stroke by 40 percent. Although more research is needed to firmly establish whether smokeless tobacco is a risk factor for heart attack and stroke, these studies suggest that smokeless tobacco may lead to serious health consequences other

Smokeless tobacco should not be substituted for cigarettes. A large study done by the American Cancer Society examined the health impact of quitting cigarette smoking versus substituting smokeless tobacco for cigarette smoking. It compared more than 110,000 cigarette smokers who quit smoking and did not use any other tobacco products with 4,400 smokers who switched from smoking cigarettes to using smokeless tobacco. After 20 years of follow-up, the risk of dying was 8 percent higher among those who switched to smokeless tobacco than among those who quit tobacco use entirely. Those who switched from smoking to smokeless also had a 46 percent higher risk of dying from lung cancer, a 13 percent higher risk of coronary heart disease and a 24 percent higher risk of death from stroke compared to those who quit tobacco entirely. In another study, using both smokeless tobacco and cigarettes had a higher risk of heart attack than the risks of using either one or the other.

It is important that people understand that there is no scientific evidence that using smokeless tobacco can help a person quit smoking. It does not provide a safer alternative to cigarettes. All tobacco products are harmful and cause cancer and there is no safe level of tobacco use.

I want to switch to media findings. Research findings show that when adolescents associate a particular behavior with people or personality characteristics they admire, they are more willing to try that behavior because adolescents identify with such people. Baseball players like many athletes serve as role models and are probably considered the quintessential users of smokeless tobacco. There are high rates of smokeless tobacco advertising in magazines such as Sports Illustrated. Considerable research has demonstrated that smoking in movies or on TV increases positive attitudes towards smoking and intentions to smoke in update of tobacco use among adolescents. There is also evidence that positive role models can help prevent smoking onset. Several studies show that celebrity health behavior such as Magic Johnson's announcement of his HÍV status or Katie Couric's televised colonoscopy on the Today show have immediate positive impacts, so actions taken by baseball players to discourage the use of smokeless tobacco could also have positive impact on youth behaviors.

We focus today on smokeless tobacco. However, the scientific evidence continues to confirm that tobacco use in any form causes cancer. All tobacco products contain harmful chemicals, and no matter how they are presented in advertisements, be warned that all tobacco products are dangerous. The only way to reduce death and disease caused by tobacco use is to prevent youth from starting to smoke and to help current smokers to quit. These must remain our highest priorities, and I appreciate the opportunity to talk to

you today.

[The prepared statement of Ms. Winn follows:]



Testimony
Before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

Hearing entitled, "Smokeless Tobacco: Impact on the Health of our Nation's Youth and Use in Major League Baseball"

Statement of

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National Cancer Institute

National Institutes of Health

U.S. Department of Health and Human Services



For Release on Delivery Expected at 10:00 a.m. Wednesday, April 14, 2010 Good morning, Chairman Pallone and Members of the Subcommittee. I am Dr. Deborah Winn, Deputy Director of the Division of Cancer Control and Population Sciences, National Cancer Institute (NCI) at the National Institutes of Health, an agency of the Department of Health and Human Services. Thank you for the opportunity to be with you today to discuss smokeless tobacco and its health consequences. I will also provide scientific evidence demonstrating the impact that media and celebrities' health behaviors have on tobacco use among youth.

Effects of smokeless tobacco on health

Use of smokeless tobacco is an established cause of cancers in the mouth (cancer of the oral cavity) and pharynx (part of the throat), esophagus, and pancreas. In 1985, the Advisory Committee to the U.S. Surgeon General examined literature on the health risks associated with use of snuff, a type of smokeless tobacco, and concluded that: "The scientific evidence is strong that the use of snuff can cause cancer in humans. The evidence for causality is strongest for cancer of the oral cavity, wherein cancer may occur several times more frequently in snuff dippers compared to non-tobacco users. The excess risk of cancer of the cheek and gum may reach nearly fifty fold among long-term snuff users."

The International Agency for Research on Cancer (known as IARC), a part of the World Health Organization, routinely convenes expert panels to evaluate the world's scientific research literature on environmental agents to determine whether exposure to those agents causes cancer. It evaluated the carcinogenicity of smokeless tobacco three times. I participated as an invited expert on all three panels. These reports are considered to be highly authoritative and are used extensively worldwide to provide the scientific basis for public health action. In 1985, IARC convened an international working group of experts in smokeless tobacco that concluded that smokeless tobacco is a cause of oral and pharyngeal cancer. In 2004, the IARC panel reaffirmed that using smokeless tobacco causes oral cancer and also concluded that smokeless tobacco is a cause of pancreatic cancer. In 2009, IARC added esophageal cancer to the list of cancer types caused by smokeless tobacco use.

The evidence that smokeless tobacco causes cancer is based on studies in human populations, studies in animal models, and studies that help us understand the biological mechanisms involved in the development of cancer. First, I will tell you about the findings in studies in human populations, called epidemiology studies. Researchers conducting epidemiology studies rely on a variety of study designs to learn more about risk factors, such as smokeless tobacco use, for disease. For example, case-control studies compare past smokeless tobacco use in a group of people with the cancer of interest to smokeless tobacco use in people without the cancer of interest. Cohort studies ask people about their tobacco use behaviors and then follow these people for a period of years or decades to determine the rates of developing cancer among groups with different tobacco use behaviors. Both case-control and cohort studies show that use of smokeless tobacco products for at least 6 months is associated with a 4-or-greater-fold increased risk of oral cancer. Some studies demonstrate that risks of oral cancer increase with increasing times per day or years of use of smokeless tobacco products.

Other important risk factors for oral and pharyngeal cancers, esophageal cancer, and pancreatic cancer are smoking and heavy alcohol intake. However, these factors do not account for the effect of smokeless tobacco on the risk of these cancers. Additionally, obesity is a risk factor for pancreatic cancer; but smokeless tobacco remains associated with pancreatic cancer risk even after we take the effect of obesity on pancreatic cancer into account.

Smokeless tobacco products are vastly different around the world. In some geographic regions such as Scandinavia, smokeless tobacco use is quite common. The IARC panel found that smokeless tobacco use was associated with an increased risk of oral cancer regardless of how the tobacco products were formulated or used in places across the globe ranging from North America to Scandinavia, Africa, and Asia.

In addition to periodontal (gum) and dental caries (tooth decay) effects, smokeless tobacco users more frequently than non-users develop leukoplakias, white patches in the mouth, and frequent and longer-term users have more patches. Leukoplakias can be pre-cancerous and, in some adults who have leukoplakia, cancer may arise. Changes in the lining of the mouth related to

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smokeless tobacco can occur in young people as well. A national oral examination survey of children ages 12 to 17 years in the 1980s found that 27% of children who used smokeless tobacco but only 0.4% of children who did not use smokeless tobacco had changes in their mouths that involved wrinkling of the surface of the lining of the mouth and color changes ranging from normal to white, or gray.

Potential reproductive effects of smokeless tobacco include decreased fetal growth and increased risk of preterm delivery and stillbirth.

Studies in laboratory animals including rats and mice also show that smokeless tobacco causes cancer. Smokeless tobacco contains tobacco-specific nitrosamines. Nitrosamines are a chemical family that includes some known carcinogens. Tobacco-specific nitrosamines are found only in tobacco products. These include 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) and N'-nitrosonornicotine (NNN). IARC has determined that there is sufficient scientific evidence that NNK and its metabolite 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL) and NNN are carcinogens in experimental animals. NNN and NNK, or their metabolites, can be found in the saliva and urine of smokeless tobacco users.

Scientists have a fairly clear understanding of the biological mechanisms whereby smokeless tobacco use causes cancer. One main pathway to carcinogenesis occurs when metabolites of chemicals found in smokeless tobacco attach to DNA, causing a genetic mutation. This mutation leads to other cellular disruptions and ultimately results in cancer. Other carcinogens found in small amounts in smokeless tobacco are aldehydes and metals.

Smokeless tobacco is addictive. The landmark 1988 report, *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*, which focused on nicotine addiction, had three major conclusions:

- 1. Cigarettes and other forms of tobacco are addicting.
- 2. Nicotine is the drug in tobacco that causes addiction.

3. The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.

Cancer is not the only adverse health affect associated with the use of smokeless tobacco. A recent report summarized the data from relevant studies in the medical literature regarding use of smokeless tobacco and myocardial infarction (also known as "heart attack") and stroke. Of the 8 studies, primarily studying men, "ever use" of smokeless tobacco was associated with a 13% increased risk of fatal heart attack. Of the 5 studies examining the incidence of stroke, ever use of smokeless tobacco was associated with a 40% increase of stroke. If non-fatal heart attacks or strokes were included in the analyses, the risks were somewhat lower. The risks did not appear to increase with greater years or frequency of smokeless tobacco use. More research is needed to assess smokeless tobacco use as a risk factor for heart attack and stroke and to determine the preventive value of strategies designed to aid cessation of smokeless tobacco use.

The American Cancer Society Cancer Prevention Study II focused on the consequences of quitting cigarette smoking versus substituting smokeless tobacco for cigarette smoking. This study compared 111,952 cigarette smokers (with no other tobacco use behaviors) who quit smoking entirely with 4,443 smokers who switched from smoking to using smokeless tobacco. After 20 years of follow-up, the risk of dying from lung cancer, coronary heart disease, stroke and obstructive pulmonary disease was higher among those who switched from smoking to smokeless tobacco use than among those who quit smoking entirely. A case-control study of risk of myocardial infarction showed that persons who smoked tobacco and used snuff had a greater risk of heart attack than those who only smoked. Even light and intermittent cigarette smoking

increase the risk for cardiovascular diseases, lung cancer, certain other diseases, and all-cause mortality. Because of these findings regarding increased heart attack risks in those who switched from smoking to smokeless and the health risks even among light and intermittent smokers, there is great concern about health consequences to persons who both smoke cigarettes and use smokeless tobacco. These additional risks could significantly impact the manner in which the risks of smokeless tobacco use would be communicated to the public.

Effects of media and celebrities' health on youth risk behaviors

Research findings show that adolescents engage in more risky behaviors, including tobacco use, to the extent that they endorse positive prototypes of individuals who engage in those behaviors. In short, when adolescents associate a particular behavior with people or personality characteristics they admire, they are more willing to try that behavior. This happens in part because adolescents identify with the prototype. Baseball players, like many athletes, serve as role models and prototypes, and are probably considered the "prototypical" user of chewing tobacco. There is also corollary evidence that *positive* role models can help *prevent* smoking onset. There are high rates of smokeless tobacco advertising in magazines read by youth, several of which are sports-related. Considerable research has demonstrated effects of smoking in the entertainment media (e.g., movies and television characters) on uptake of tobacco use among adolescents. Exposure to smoking in movies increases positive attitudes toward smoking and intentions to smoke. Epidemiologic studies consistently demonstrate a dose-response relationship between exposure to smoking in movies and smoking initiation, after controlling for peer and family smoking, parenting style, sensation seeking, and demographic characteristics such as gender and ethnicity. These findings have also been replicated in other cultures.

Several opportunistic studies show that celebrity health behaviors (e.g., Magic Johnson's announcement of his HIV status and Katie Couric's televised colonoscopy on the Today show) have immediate behavioral effects.

Although I have focused today on smokeless tobacco, the scientific evidence continues to confirm that tobacco use in any form causes cancer. NCI encourages anyone who does not use tobacco not to start and encourages anyone who does use tobacco to quit. There are many effective approaches at the community and the individual level to prevent tobacco initiation and to quit.

Thank you for this opportunity to present this information to you. I would be happy to answer any questions.

Mr. PALLONE. Thank you, Doctor.

We are going to now take questions, 5 minutes from those who gave opening statements, and we have a few members who passed so they get 8 minutes for questions, and I will start with myself.

Both of your testimony indicates strongly that smokeless tobacco causes cancer, and we have talked a lot about smoking tobacco and the different chemicals that make up a cigarette that cause cancer. Now, you started how it works with chewing tobacco when there is no smoking relation and how that causes cancer, but just explain it to me again because it wasn't too clear to me. What is it that causes the cancer? And then you specifically mentioned pancreatic which, you know, I often mention pancreatic at our hearings because my mom passed away from pancreatic cancer, and most people don't know, you know, when you ask what is the cause of pancreatic cancer, generally speaking, the answer is, we don't know, so if you would just reiterate some of that.

Ms. WINN. Sure. I will start with pancreas cancer first, and important causes of pancreatic cancer are smoking and smokeless to-bacco. Heavier weight is also associated with pancreatic cancer risk but there is certainly a great deal more than we need to learn regarding pancreatic cancer risk because we know that it is often

identified at an advanced stage.

With regard to how smokeless tobacco causes cancer, tobacco-specific nitrosamines are—nitrosamines are a category of carcinogens, and tobacco-specific nitrosamines are found only in tobacco products, and tobacco products contain these. They have been found in experimental animals to cause cancer. We also have done experiments that show the progression from metabolites of these nitrosamines, which attach to DNA that causes a replication error in the DNA when the DNA—

Mr. PALLONE. But in other words, you don't inhale it, so how does it get into your system?

Ms. WINN. Because you are ingesting.

Mr. PALLONE. Just through your stomach, in other words, through your digestive system?

Ms. WINN. Right.

Mr. Pallone. And then, you know, we get these muddled messages about substituting smokeless for tobacco for just smoking. I mean, you have made it quite clear that you think that they are both dangerous, but what about this idea that somehow you can substitute smokeless and that somehow weans you off actually

using cigarettes?

Ms. Winn. There certainly are differences in risks between smokeless tobacco and smoking. However, what counts is the potential effect on the population of giving advice to recommend using smokeless tobacco. We have to consider that that type of a message may delay or halt some people from quitting smoking who might have quit smoking through some other means. We also know that smokeless tobacco is a gateway to smoking among young children. For example, in one study of adolescent boys, the boys who used smokeless tobacco and no other tobacco product were three times more likely 4 years later to be using—

Mr. PALLONE. Because there are studies that show that the perception of risk from smokeless tobacco is declining among youth, so

bottom line, they may figure well, I better not smoke a cigarette but I will chew instead, and then they get addicted. We can't give the impression out that somehow that is OK because what you are saying is, it often leads to smoking cigarettes.

Ms. WINN. Absolutely, and there are no safe levels, and smoke-

less tobacco causes a variety of diseases.

Mr. Pallone. Let me ask Dr. Pechacek, your testimony explains how the scientific evidence clearly shows that smokeless tobacco is hazardous, that 28 carcinogens have been identified in smokeless tobacco. They cause specific physical feelings and effects, cardiovascular effects, fatal heart attacks. I mean, it seems to me that this is totally contrary to what a baseball player or any athlete would want to do, so how does tobacco use specifically affect the performance of an athlete, in particular a baseball player? Because young athletes, if they are paying attention, it would seem to me that it would hurt their athletic performance, not enhance it in any way. So what is the message there in terms of what it means if you are young and you start using this stuff?

Mr. PECHACEK. Well, first of all, our advice to both major league or youth baseball players is that like any other person, anyone who is using any form of tobacco, we would encourage them to quit as early in life as possible. It is especially important for the baseball players who are setting an example because like parents, teachers and coaches, they serve as role models to children and adolescents.

With respect to the specific aspects on performance, I can provide you more detail on that from the previous work that has been done in the Surgeon General reports but the key point is that all users, particularly young adolescents and young adults who are following those role models, need to be aware that all forms of tobacco are addictive and cause cancer and serious health effects and that quitting all forms of tobacco use as early in life as possible will be very beneficial to their long-term health.

Mr. PALLONE. But I think they almost get the impression, young people, that somehow it enhances athletic performance and clearly

it is the opposite in terms of performance.

Mr. Pechacek. Well, the aspects of this and how youth perceive the product have been reviewed in past Surgeon General reports, most in detail in the 1994 Surgeon General report on the impact of tobacco on youth and young people. We are currently updating that report, which will be out next year, and are going into how these current patterns of smokeless tobacco are being perceived by youth and are impacting their overall decisions about what they are doing with using all tobacco products.

Mr. PALLONE. Thank you. The gentleman from Illinois.

Mr. ŠHIMKUS. Thank you, Mr. Chairman.

Dr. Pechacek and Dr. Winn, I am getting conflicting briefing things. You are listed as doctors but in here it says Ph.D.'s. Are you medical doctors that have Ph.D.'s, or what is the title here?

Mr. PECHACEK. Ph.D., so I am an epidemiologist. Ms. WINN. I have a Ph.D. in epidemiology.

Mr. Shimkus. Great. Thank you.

Dr. Winn, we have had hearings, and I am new in the ranking member position, on the NCI and we appreciate the great work that the cancer institute does and we really are starting to focus on cost-benefit analysis, where the money goes, biggest return on investment versus the politicizing of some research dollars, and we will get more involved in that in the future, but what is the deputy director of the Division of Cancer Control and Population Sciences?

For the layman, what does that mean?

Ms. WINN. That means that we are the division that is responsible for understanding environmental exposures and genetic factors that may be linked to cancer in human population studies. We are responsible for the cancer registry system. We are responsible for understanding the effects of cancer on people's outcomes in terms of quality of life, physical functioning after cancer. We are responsible for understanding the access to cancer care, quality of cancer care in the United States.

Mr. Shimkus. Thanks. I think that helps. But in this hearing, we are focusing on Major League Baseball but there are other environmental issues that we could probably address. I don't want to get raked over the coals but I represent deep southern Illinois, and of course NASCAR is well known for its advertising. Country and western music—I think most people identifying chewing tobacco use with the West and cowboy use and all those. Have you done similar focuses on or has our committee or are we just focusing on one area, Major League Baseball, and not looking at other environmental impacts?

Ms. Winn. Most of the research that I presented was not done in tobacco in baseball players. Virtually all of the research that I have presented has either been in national surveys of school-

children or other populations.
Mr. Shimkus. Great, and let me follow up with this, and then I will go to Dr. Pechacek. In your testimony, you said any tobacco use—I mean, my colleague, Mr. Buyer, is really on this risk avoidance and mitigation stuff but your testimony says that patches or nicotine gum is not any help in reducing nicotine and tobacco use for anyone.

Ms. WINN. No, there are effective ways of quitting use of tobacco. Mr. Shimkus. That is fine. That is really I wanted to get record of. What you stated, I thought that you—and I think a lot of us would say, no, we want to encourage people to eliminate nicotine input over time, and most people can't do cold turkey. Some can't. But I think there are some risk avoidance and mitigation-type stuff and I know my colleague will follow up on that.

Dr. Pechacek, according to a December 2009 report from the Campaign for Tobacco Free Kids, only one State currently funds a tobacco prevention program at the level recommended by the CDC.

Do you agree with that assessment?

Mr. PECHACEK. We are continuing to work with our States, and it depends on what year. The most recent put out by the Campaign for Tobacco Free Kids, their criteria found that only one State met

our guidelines for recommended funding.

Mr. Shimkus. And so our focus probably should be, if we are serious about this, is calling in the States and asking them why aren't they fully funding the tobacco cessation plans as recommended by the CDC. Don't you think that would be another good approach?

Mr. Pechacek. The CDC is very clearly on this recommendations to the States and about what works and what levels of investment would be most effective. We are in regular dialog with our States about comprehensive State programs and local tobacco programs that use the evidence-based approaches that have been shown to be effective and to be reducing rates of both youth and adult tobacco use.

Mr. Shimkus. Thank you. That goes to my opening statement where I talk about the master settlement agreement, which would be about \$206 billion over 25 years that the tobacco companies would pay. Don't you think it is pretty egregious that only 30 percent of that money has gone to health care and only 3.5 percent of those funds go to tobacco control like smoking cessation and education programs?

Mr. PECHACEK. CDC has been very consistent in providing evidence both to policymakers and individual States and to the other

groups

Mr. Shimkus. You are being very political, and I appreciate that. My point is, the State attorneys general have a master settlement agreement which should have brought billions of dollars into States. The States have used that money to do other things other than health care and education. You have also testified that you have recommended to States that they do an educational program, believing that an exponential decrease in tobacco use by kids would occur if they would at least fully fund tobacco cessation and educational programs. I think if you go to the conclusion here, we have States who received billions of dollars who have not funded health care, who have not done cessation programs, and now to a point of we see an uptick in at least chew tobacco increase by kids, which is another example of us failing to do the job that we are asked to do and in essence took money for, thus showing how inept we are at doing the jobs we are asked to do by the public, and I yield back my time.

Mr. PALLONE. Thank you.

Ms. Eshoo.

Ms. Eshoo. Thank you.

Dr. Winn and Dr. Pechacek, can you tell us what CDC and the National Cancer Institute have observed with regard to use of

smokeless tobacco by teenagers?

Mr. PECHACEK. In my testimony, I reviewed the latest evidence that multiple surveys have shown an increase in smokeless tobacco use overall in youth populations. The data that we are going to be releasing this summer is the National Objective Youth Use Tobacco Survey showing an increase in smokeless tobacco use among adolescent males, high school males overall and white students.

Ms. Eshoo. And in the minority community?

Mr. Pechacek. The NSDUH survey has found that when it is looking at the recent increases nationwide in smokeless tobacco use over the last 4 to 5 years, that the greatest increases have been in non-Hispanic white and Hispanic males. So while there have been traditionally higher rates of use in some other demographic groups, non-Hispanic white males and Hispanic males are the ones who appear to be showing the greatest increases in recent years.

Ms. Eshoo. Do you have any thoughts on what accounts for these increases in smokeless tobacco use? I mean, obviously we have representatives from baseball here today. I think that everything that adults do from being a parent to obviously anyone in sports is a—you know, they are the gladiators of the 20th and the 21st century. So they heavily influence young people. I think we do as well. Congress isn't always known for putting forward all of its best but certainly when there is something that goes wrong here, by example of an individual member, that says something to the people of our country and obviously young people. So do you have anything that you want to tell us about what you think accounts for these increases in smokeless tobacco use?

Mr. PECHACEK. Yes. As the comments that in my written testimony which we submitted is that these recent upticks need to be placed in the changing context of tobacco use in this country. Smoking rates are down and restrictions on smoking in public places are increasing, particularly in your State of California. And overall we have observed that there is an increasing social accept-

ability of smoking.

However, while these things are occurring, there have been significant changes in the smokeless tobacco industry and how smokeless tobacco products are marketed. Until 2006, smokeless tobacco was largely produced by companies that did not manufacture cigarettes. Now major cigarette manufacturing companies produce and sell most smokeless tobacco products in the United States. In recent years, these companies have been marketing smokeless tobacco and snus named after their leading cigarette brands. The advertising and promotional spending on these types of moist snuff products increased by 50 percent between 2005 and 2006, the latest year in which these data have been reported. This timing is significant because it was at this point in time that this transfer from the smokeless tobacco manufacturers being independent of cigarette makers started. Of particular concern is that many of these new smokeless products are being marketed in a way for smokers to satisfy and sustain their nicotine addiction when they are in settings that they cannot smoke.

Additionally, to your point, while we do not have any new and more detailed studies with respect to sources of influence, the two largest groups where we are seeing the increase are in non-Hispanic young men and in Hispanic men. Additionally, we know from

other data that——

Ms. Eshoo. Let me just ask you about that. It is a little con-

fusing. Non-Hispanic young men and Hispanic older men?

Mr. PECHACEK. No, 18- to 25-year-old white and Hispanic. We call it non-Hispanic white to separate it from Hispanic that self-identify Hispanic. So both Hispanic and non-Hispanic young men who are—

Ms. ESHOO. You know what? It is got to be a little simpler. It sounds—I don't understand what you are saying. Let me put it that way. Name the groups. Name them.

Mr. PECHACEK. White and Hispanic young men 18 to 25 years

Ms. Eshoo. Increase?

Mr. Pechacek. Are increasing more than anybody else.

Ms. ESHOO. All right. Well, I think that these are really disturbing trends. I just leaned over and I said to my staffer a little while ago, when it comes to baseball players, why don't they just chew gum, I mean, if they feel like they need to chew something, and she responded because they are addicted. So clearly I think there is a nexus here. I don't think it has everything to do with those that play baseball but on the other hand, they are individuals that are really looked up to and young people always want to look in the mirror and see the reflection of their heroes. So I think that we need to work hard to find a way to reverse these trends and make sure that smokeless tobacco really—when you come back in succeeding years, that we can claim that there is a huge decline. This isn't something that is healthy.

Anyway, thank you very, very much for your testimony. Dr. Winn, I am over my time so I don't know if you wanted to add something to it, but maybe you can when someone else questions

you. Thank you very much.

Thank you, Mr. Chairman. Mr. PALLONE. Thank you.

The gentleman from Kentucky, Mr. Whitfield.

Mr. Whitfield. Thank you all for being with us today. I think that Congress has given the regulators a lot of opportunities to make great progress in this area. It is true, Mr. Pechacek, isn't it, that on June 22, 2010, it will be illegal to sell a smokeless tobacco product to anyone under the age of 18? Is that correct?

Mr. Pechacek. Yes, that is my understanding of the bill, yes.

Mr. Whitfield. Now, many of us were not aware of it but in the stimulus bill, which certainly was about creating jobs, there was \$650 million set aside in there to address clinical and community-based prevention and wellness strategies, and it is my understanding that that money was given to HHS and CDC to get this money out there. So my question would be, number one, of that money, how much went for tobacco strategies in the States or the local communities?

Mr. Pechacek. I don't have those detailed numbers. We would be happy to provide those to you and your staff in this committee.

Mr. Whitfield. When this money became available, did you in your regulations set out how much money should be spent on nutrition and how much money on tobacco, how much money on obesity or anything like that?

Mr. PECHACEK. Well, yes, we can provide you the details on the funding announcement. The priorities were smoking prevention and obesity—

Mr. WHITFIELD. You said a certain amount of money for each one of those in your regulations?

Mr. PECHACEK. There were funding guidelines that were put out to the States and the actual numbers we can get you in terms of how the breakdown on that—

Mr. Whitfield. How much money remains to be spent of that 650 million?

Mr. PECHACEK. The application awards I believe are completed now and are available that we can make available to you. I think it all has gone through funding announcements and awards.

Mr. WHITFIELD. Well, how much money has already been sent out?

Mr. PECHACEK. I would have to get our administrative people to give you the details on that since the—applications have been reviewed. However, the process of actually getting the money into States budgets, you know, is an administrative function.

Mr. WHITFIELD. So you don't know how much is going to be going out in grants and you don't know how much money has already been distributed to States and local government under this pro-

gram?

Mr. PECHACEK. With respect to that \$650 million, all of that money was put into funding announcements, so yes, all of that is

going out.

Mr. Whitfield. Well, you know, one of the things that—I mean, this is a big problem obviously, smokeless tobacco and its impact on health, but to put this money in the stimulus bill, and then I read an article that in Washington, D.C., they received \$977,000 and created one full-time job, and what did they do with that money? They bought BlackBerrys for people so that they could be in touch with their smoking counselors. Now, do you consider that a good utilization of the money?

Mr. PECHACEK. I don't have any details on that specific case. However, there is very specific guidance that is provided in the funding announcement from CDC with regard to the most efficacious, comprehensive strategies that have been shown to be effec-

tive and cost-effective in reducing tobacco use.

Mr. WHITFIELD. Although we were not aware of it, in the health bill itself that passed, in the first 5 years there is over \$5 billion set aside for a grant program to go out addressing the so-called maps intervention for communities program. Where are you all in developing the regulations for that?

Mr. Pechacek. Well, first of all, a point of clarification, CDC is not a regulatory agency. We are a public health agency. With re-

spect to—

Mr. WHITFIELD. Well, HHS, you know, where they are on it.

Mr. Pechacek. The specific aspects of that overall program——Mr. Whitfield. Will you be involved in distributing that grant

Mr. WHITFIELD. Will you be involved in distributing that gramoney? Will CDC be involved?

Mr. PECHACEK. CDC has a role in working with HHS and the White House with respect to guiding the evidence-based interventions that have been found to be most effective.

Mr. Whitfield. Well, I know in your position, you are involved with smoking and health. I want to ask one other question. One of the guidelines that they put in the area of nutrition in spending this money is urging communities, local communities to reduce density of fast-food establishments. How do you propose that that be done? How do you hope that will be accomplished?

Mr. PECHACEK. That is outside of my division. With respect to

Mr. Pechacek. That is outside of my division. With respect to issues of tobacco, I can give you more specifics, but we can provide you feedback on what we are doing on density of fast-food res-

taurants if you would like.

Mr. WHITFIELD. Thank you. I see my time has expired. Mr. Chairman, if there is not an objection, I would just like to insert for the record a publication of the National Convenience Store As-

sociation going into some detail about the health portion of the stimulus bill as well as the Washington Times article about the BlackBerry.

[The information appears at the conclusion of the hearing.]

Mr. Pallone. Without objection, so ordered.

Mr. Engel.

Mr. ENGEL. Thank you, Mr. Chairman.

Dr. Winn, your testimony describes baseball players, and I am quoting you, "as the prototypical user of chewing tobacco." You also note that, and again, I quote from your written testimony, that "adolescents engage in more risky behaviors including tobacco use to the extent they endorse positive prototypes of individuals who engage in those behaviors." I know that Mr. Manfred from Major League Baseball and Mr. Prouty from the Major League Baseball players' union are in the audience for this testimony and we will hear from them later, but I want them to hear your views on this matter, so let me ask you this very simple question. When teenagers and young adults see Major League Baseball players using smokeless tobacco, does it make it more likely that these young people will themselves become users?

Ms. WINN. That is likely based on evidence that shows that peers and parents and other role models for children influence their use

of smokeless tobacco.

Mr. ENGEL. So it was an obvious question. I know that would be your answer. So let me also ask another obvious question. Do you believe that if Major League Baseball and the players' union were to agree to ban the use of smokeless tobacco on the field and in the dugout, would that result in a reduction in smokeless tobacco use among teenagers?

Ms. Winn. Well, certainly the evidence from Katie Couric's colonoscopy and Magic Johnson's HIV status definitely had a positive impact on the U.S. public in terms of taking preventive measures, so it seems likely by analogy that that would have a positive

effect on youth in the United States.

Mr. ENGEL. Thank you.

Dr. Pechacek, do you have any thoughts of the impact of the use

of chewing tobacco by Major League Baseball players?

Mr. Pechacek. The evidence that we have reviewed in the 1994 Surgeon General report as well as other documents since then shows that professional athletes in certain sports including baseball have traditionally had high levels of smokeless tobacco use. Athletes serve as role models for youth and smokeless tobacco manufacturers have used these imageries in advertising testimonials by featuring athletes in sports to make smokeless tobacco products appear attractive to youth. Teens to mimic the behaviors of those who they look up to and identify with including baseball players and athletes. While smokeless tobacco use was prohibited in minor leagues in the early 1990s, this policy has not been extended to major leagues.

Mr. ENGEL. Thank you.

Dr. Winn, I have heard reports that in Sweden, significant numbers of people are quitting smoking and using smokeless tobacco and that the country's rates of lung cancers have gone down. This

might seem to support the argument that smokeless tobacco is a form of harm reduction. This argument rests on the idea about the use of smokeless tobacco is good because the risks of death and disease from using smokeless tobacco are less severe than the risks of death and disease from using cigarettes. So I want to ask you about that. Does that idea match up with reality? Is smokeless tobacco really a form of harm reduction, especially when we are talking about children who are not using any form of tobacco? I think that this notion of harm reduction becomes even more untenable in the case of young athletes in general. My understanding is that young athletes are less likely than the general population to smoke cigarettes but they are more likely to use smokeless tobacco. I want to hear your thoughts on that.

Ms. WINN. Well, I have reviewed the report, the Swedish statistics, and I want to note that the claim that because the rates of smokeless tobacco have gone up that that has influenced the rates of smoking going down. Well, I want to emphasize three fundamental facts. One is that all tobacco products are hazardous and there is no safe level, and what we need to do is prevent its use and help them quit. But with regard to the Swedish situation, the Swedish National Institute of Public Health found in their survey that of Swedish women who use snuff, that is a relatively small portion of women in Sweden use snuff, but smoking rates have dramatically declined in Swedish women, indicating that snuff is actually not responsible for the decline in smoking. There is a continuum of risk associated with both smokeless tobacco and smoking but we are most concerned about issues related to dual use of smoking and smokeless tobacco and on smokeless tobacco as a gateway for children.

Mr. ENGEL. So in the case of young athletes who don't smoke cigarettes but use smokeless tobacco because they see Major League Baseball players using it, would it be fair to say that smokeless tobacco use significantly increase their health risks?

Ms. Winn. Yes. It increases their risk of oral lesions in their mouth and many oral lesions have the potential to develop oral cancer.

Mr. ENGEL. Thank you. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

The gentleman from Indiana, Mr. Buyer.

Mr. BUYER. Thank you, Mr. Chairman.

Dr. Winn, I am trying to reconcile a couple of comments. You acknowledge that there is a continuum of risk within tobacco products, smoking to smokeless, pharmaceutical and quitting, a continuum of risk. You acknowledge that, correct?

Ms. WINN. There is a continuum of risk associated with—

Mr. BUYER. From very high risk to very low risk. You acknowledge that?

Ms. WINN. Quantitating it at the higher load, they all have risks. Mr. BUYER. You acknowledge that there is a continuum of risk from very high risk to very minimal risk. Do you acknowledge?

Ms. WINN. Very high risk to moderate risk.

Mr. BUYER. To moderate risk, so if I can say in proving science that there is a product on the market that would remove 99 percent of the nitrosamines, you would define the 1 percent as moderate?

Ms. Winn. All smokeless tobaccos have some risk of health effects.

Mr. BUYER. That is correct. I concur with that. Now, let me go back and acknowledge this, and let us not play games. Do you acknowledge that there is a continuum of risk from very high risk to very low risk?

Ms. Winn. Of specific—

Mr. BUYER. The health effects and the use of tobacco products. Ms. WINN. Some tobacco, for example, chronic obstructive pul-

monary disease is not caused by smoking tobacco.

Mr. Buyer. I am not going to quibble with you, because it appears that if you won't even acknowledge that there is a continuum of risk, then you are placing yourself in a camp of complete abstinence. Now, I will concur with you that tobacco products are not healthy. I concur with that. But to ignore that there is a continuum of risk from very high risk, cigars, to very low risk, which would be a product—let me ask you this question. If you able to put a product on the market that reduces the nitrosamines, does that improve the chances of one's, or does that eliminate then health risks?

Ms. Winn. What causes us concern under those circumstances is the population effect that might be influenced by people smoking and adopting smokeless tobacco—

Mr. BUYER. Do you acknowledge that if I can reduce the

nitrosamines in a product that I can reduce the risk?

Ms. WINN. There is no epidemiologic evidence that shows that that is the case. It is important that nitrosamine levels be reduced.

Mr. BUYER. So are you saying to me then that an orb or a stick that has reduced 99 percent of the nitrosamines is just as harmful as smoking a cigar? That is what your statement is saying.

Ms. WINN. Yes.

Mr. BUYER. And you concur with that?

Ms. Winn. Assessing nitrosamine levels or reduced nitrosamine products is under the purview of FDA so I would——

Mr. BUYER. All right. Great. Your staff just gave you that so you

could read it. But just answer the specific question.

Ms. WINN. We don't know that there is any—there is no level of nitrosamines that is known to be safe.

Mr. BUYER. Wow. So you are unwilling to recognize differentials of risk within tobacco products? I guess that is what I am hearing from you. You do not acknowledge that there is a differential of risks among tobacco products?

Ms. WINN. There is a continuum of risk.

Mr. BUYER. Thank you. We got there, didn't we? We got there. There is a continuum of risk. Now, why is that important? It is important because as a country, those of whom are the advocates of an abstinence approach are locking us in to a system of failure. If we only have up to 7 or 8 percent of whom want to quit, that is failure in my eyes. And so if we can actually migrate a population from smoking to smokeless to eventually quitting, that is impor-

tant. Now, no one wants our teens or adolescents or youth or you name it to gain access to these products. So I concur with you on

Mr. Chairman, I respect you because you are open to many different distillations of thought and I believe in personal cultivation, I believe in the scholarship maintenance of our knowledge. It improves our self-worth and it is our quest for a greater understanding and ration and reason and tolerance to ameliorate. I am going to offer some differing views and I would like to offer them for the record. So what I would like to offer for unanimous consent to be placed into the record, first is a report called a Broken Promise to Our Children. It is an 11-year analysis of how the States are not spending the MSA settlement on tobacco prevention. I ask unanimous consent this be placed into the record.

Mr. PALLONE. Can I just ask, are some of these things going to be part of the printed record or can we just do them—how does it work? It looks like it is pretty extensive. We can? OK.

Mr. Pallone. Without objection, so ordered.

Mr. Buyer. I would also ask unanimous consent that the Strategic Dialog on Tobacco Harm Reduction: A Vision and Blueprint for Action in the United States by Mitch Zeller and Dorothy Hatsukami also be entered into the record.

Mr. Pallone. Can I look at that? Go ahead. Why don't you con-

Mr. Buyer. I would also ask unanimous consent that the Smoke-Free Tobacco and Nicotine Products Reducing the Risk of Tobacco-Related Diseases and by Scott Ballin be entered into the record.

And last, I would unanimous consent—not last. I would ask unanimous consent that the brief report on evidence against a gateway from smokeless tobacco use to smoking by Dr. Brad Badu also be entered into the record.

Mr. Pallone. I am just taking a minute here because I noticed they are pretty extensive and I just want to make sure—OK. Is that everything?

Mr. BUYER. Yes.

[The information appears at the conclusion of the hearing.]

Mr. Pallone. Without objection, so ordered.

Mr. BUYER. Thank you.

Mr. Pallone. Next is our vice chair, Ms. Capps.

Mrs. Capps. Thank you, Mr. Chairman.

I want to thank our witnesses for their excellent testimony. I particularly want to thank the second panel for your patience in waiting through this first one, which is our process here in this subcommittee.

I have a question for each of you and I am going to start with Dr. Pechacek. I was particularly alarmed by your statement during your testimony that the perceived risk of harm from smokeless tobacco has decreased, actually decreased among teenagers. You know, we have taken such, I think, quite significant steps through enactment of recent health reform legislation to invest in greater wellness and prevention strategies as a whole. We have this opportunity with some of these new parts of the reform legislation. I would like you to give us some advice of what strategies we could take in our local communities through our health clinics expansion and so forth to reverse this very alarming trend.

Mr. Pechacek. Comprehensive State and local tobacco control programs that we have defined in our multiple CDC documents give evidence-based approaches that have been shown to be effective in reducing tobacco use overall as well as smokeless tobacco. These approaches change environmental cues in ways that make tobacco use in any form less acceptable and quitting easier. These types of programs include educational strategies as well as public policy changes that send a clear message to youth that smokeless tobacco along with all product use are dangerous to their health. On a concrete level, CDC has been communicating a clear message that there is no safe form of tobacco use and that any tobacco product is hazardous to health. For example, the CDC has recommended since the mid-1990s that schools implement 100 percent tobacco-free policies that eliminate all tobacco products by faculty, staff and students including smokeless tobacco on school grounds, at school events including sporting events. CDC is closely monitoring trends in the smokeless tobacco use and how different marketing campaigns are impacting youth and providing this information to our States so they can more effectively provide informational campaigns that can turn around this negative trend.

Yes, we are concerned about this downturn in perceived risk which is in 8th, 10th and 12th graders with the largest drop in 10th graders. This indicator has been a very reliable leading indicator of this type of question, not only for smokeless tobacco but for cigarettes, alcohol, marijuana and other behaviors. Therefore, this

downturn does indicate reason for concern.

Mrs. CAPPS. Thank you. I have a feeling our second panel is going to elaborate on some of the specific ways that we can really get this message across at such a key age group and their habits of course will impact their health for a lifetime. I appreciate that from the CDC.

Now, a question for you, Dr. Winn. During our committee's debate on giving the FDA authority to regulate tobacco products, some of our colleagues were advocating policies promoting this socalled lower risk of tobacco products. I think you heard some of that voiced today as well. In your testimony, you clearly outline that transitioning from cigarettes to smokeless tobacco actually contributes to more negative health outcomes in many cases, and just for the record, I would like to have you elaborate a bit more on this strategy because this is a myth that keeps rearing its head, and doesn't it make more sense to provide comprehensive education about all tobacco kind of in line with what Dr. Pechacek was saying to include information about why it is all dangerous and how to be empowered to resist and reject it?

Ms. WINN. Right. Certainly the evidence to date, and it is a growing literature, indicates that using both behaviors increases risk of several chronic diseases, and that is a great concern that we have with regard to some of the trends in youth using both products together. This is a very concerning trend that we have. Is

there an additional specific question?

Mrs. Capps. No. Well, I think you are highlighting the goals for having comprehensive education. In other words, if you are talking about stopping smoking of cigarettes or never starting with young people, you want to also make sure that they don't see an alternative. It all has to be presented at one time. Otherwise they are going to fall prey because the targeting of advertising, and we have seen this with cigarettes as well, is so insidious with young people, the targeting of just the right images using athletes, which is understandable. They are heroes. My grandkids look up to them. If they even see them without even saying a word chewing, that will be in their subconscious to be tempted to try, so I appreciate that very much.

Ťhank you. I yield back. Mr. PALLONE. Thank you.

The gentlewoman from Tennessee, Ms. Blackburn.

Mrs. Blackburn. Thank you, Mr. Chairman. I appreciate that. I have got just a couple of questions that I want to direct to the two of you together, and again, thank you for your patience for this morning. The CDC's youth risk behavior survey measures smokeless tobacco among high school students. That is correct, right?

Mr. PECHACEK. Yes, 9th through 12th graders. Mrs. Blackburn. OK, and it also publishes data for individual States and a number of major cities, and as we were getting ready for the hearing, I looked at the data that was there for several Major League Baseball cities including Baltimore, Boston, Chicago, Detroit, Houston, L.A., Miami, Milwaukee, New York, Philadelphia, San Diego, San Francisco and Washington, D.C. I wish that Nashville or Memphis was included in that list but it is not, but we will talk about that another day. So given the topic of this hearing and what we were going to be discussing and looking at your survey, I found something very interesting. Every single one of those major league cities, every one of them, every single one of them, believe it or not, had a teenage smokeless tobacco rate that was below the national average, and I found that so interesting. The major league cities have a smokeless tobacco rate that is below the national average. And the same is true when you go back and you look at the previous CDC surveys, which are published every 2 years. It was true in 2007, it was true in 2005, it was true in 2003, it was true in 2001. You know what? There is not one single exception, not one. Every single Major League Baseball city in every single year where the CDC survey measured, it was lower than the national average. So if baseball players are having such a dramatic impact on teenage smokeless tobacco use, why would evidence of this impact only occur in places where there is no Major League Baseball team? I want to know if there was any finding in your work that would shed some light on that, and I would love to hear from both of you on that.

Mr. Pechacek. Thank you for your question. Yes, there is evidence that will help explain that.

Mrs. Blackburn. Wonderful. Elaborate.

Mr. Pechacek. First of all, rates of smokeless tobacco use traditionally have been higher in more rural and other parts of the country. We can provide you more detail on the geographic breakdown. Additionally, the rates of smokeless tobacco use among African American populations is much lower than overall in other demographic groups. So those two factors alone just by the demographics of the major cities that you have mentioned result in a differential.

When we are looking at the influence of any factor, what we are looking at is the exposure. One of the main things that we have to be aware of in the exposure is the primary exposure is not necessarily attending the baseball games but watching them on the media so that the geographic distribution of the imagery exposure is quite different than the location of the stadium. Now, we do not have any published studies with respect to number of minutes watching Major League Baseball and its impact but the data that has been done will show that it is the youth that are paying attention to baseball that may be at the greatest risk.

tion to baseball that may be at the greatest risk.

Mrs. Blackburn. OK. So let me ask you this. Looking also at your surveys, you see that the use went down from 11.5 in 1993 to 7.9 in 2007 and from 20.4 among teenage boys the smokeless to-bacco rate has dropped from 24.4 in 1993 to 13.4 in '07. So what factors have been working so well in recent years? What is it that is being done in recent years that is causing young people to choose not to use smokeless tobacco? Is it education? Is it parents? Is it outreach? Was it the tobacco settlement agreement? What do you

think has helped to spur that kind of drop in usage?

Mr. Pechacek. First of all, the types of programs that work for smokeless tobacco are very similar to those that work for preventing all tobacco use, cigarettes and other forms. What we have found is that the comprehensive types of programs that focus on public policy change such as smoke-free environments and other types of things that are sending a clear message that all tobacco use is harmful is reaching youth. The programs in the mass media are particularly effective that are providing broad messages about the risk of tobacco use such as the legacy media type of campaign as well as the State-specific campaigns. All of those types of things are effective in preventing cigarette use and smokeless tobacco use. One of the things that is of concern is that while we have been seeing a decline in both cigarettes and smokeless tobacco use through about 2005, the data that will be published this summer from the youth risk behavior shows a reversal of those trends that you were citing, and then when you look at all the data points including the 2009 data point that will be released this summer, that the rates of smokeless tobacco use among high school males has reversed and is now increasing with the point of deflection or the statistical point of change being 2003. So for a number of years the pattern in multiple surveys is showing an increase of smokeless tobacco use among youth in general, particularly males, particularly white and Hispanic males.

Mrs. Blackburn. Thank you very much. I am over my time. I will yield back. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

The gentleman from Maryland, Mr. Sarbanes.

Mr. SARBANES. Thank you, Mr. Chairman. I have a couple of sort

of random questions here.

Just following up on the surveys, the cities that my colleague mentioned where the rate of smokeless tobacco use is lower than the national average, is it however the case that if you looked at the use among the two populations you cited in Hispanic youth and non-Hispanic white youth that in those cities you would find evidence of this trend of an increase even if it wasn't carrying a sta-

tistic above the national average?

Mr. PECHACEK. The individual data will be released this summer with respect to all of the locations including the national data. What we are seeing in the overall pattern is yes, across the Nation in non-Hispanic white and Hispanic youth we are seeing the uptick. This uptick has been going on for several years now. With respect to patterns in specific communities, we have not had those levels of analyses yet but we certainly are willing to look into that.

Mr. SARBANES. So it is at least possible that even though the increase hasn't taken the statistic above the national average in some of those places cited that the fact that there is an increase could be connected to the use by role models such as Major League

Baseball players.

A lot of the discussion is focusing on Major League Baseball, you know, responsibility to implement restrictions on the use of smokeless tobacco because of the role model status that the players have. This isn't really a question, it is just kind of an observation, and I guess the second panel is in a position to speak to this better. I would just think that the owners and team management and the league itself would be interested, given the kind of investments they make in their players financially and otherwise to put these kinds of limitations, regardless of the impact it is having on youth or other members of the public, given the litany of effects that you have been able to describe today in terms of how harmful it can be and how quickly the conditions that it causes can develop. That is the other thing that is striking when you look at the testimony that you have presented, so I just want to introduce that theme here that it is not simply about the example that is being set that ought to cause us to call upon Major League Baseball. I would just imagine that as a matter of good practice and good business management on the part of the league and the owners that they would want to institute this. It has been done at the minor league level so somebody has figured out that it is not a great thing because it is not the role model aspect of the minor league baseball players that led to that ban being put in place. It must have been some other consideration like the health of the players. So I just don't understand why that wouldn't apply to the major league players.

Let me ask you, is the restriction on advertising on television and so forth that applies to smoking tobacco, does that apply as well to smokeless tobacco?

Mr. Pechacek. The new FDA legislation signed last year extends the restrictions more completely to smokeless tobacco.

Mr. Sarbanes. OK. So when you think about—I mean, I was reading some of the testimony, one World Series game somebody calculated there was 9 minutes of tobacco use that would have been viewed by someone who watched the whole game on the part of the players. That is like a giant loophole, isn't it, in terms of being able to distribute this kind of imagery over the airwaves? Is it fair to characterize it that way?

Mr. PECHACEK. I believe our next panel is going to go into that in more detail, but in general as we have reviewed in recent Sur-

geon General reports from 1994 on, those types of imageries do reach youth and do have an impact.

Mr. SARBANES. And more sinister, arguably, because it is more kind of just woven into the fabric of what they are seeing than a full-force advertisement might be.

Thank you, and I yield back my time. Mr. PALLONE. Thank you, Mr. Sarbanes.

I guess that concludes our questions for the first panel, but we do want to thank you, and you may get questions from us, written questions, within the next 10 days that we will ask you to get back

to us as soon as you can, so thank you very much.

If I could ask the second panel to come forward and see where your nametags are there. Take your seats and we will proceed. Let me introduce each of you. First on my left is Gruen Von Behrens, who is from Stewardson, Illinois. Thank you for being here. And then we have Robert D. Manfred, Jr., who is executive vice president of labor relations and human resources for Major League Baseball. And then we have David Prouty, who is chief labor counsel for Major League Baseball Players Association. And then the famous, it says here Joseph Henry, but Joe Garagiola, Jr., who is a Major League Baseball announcer and a former Major League Baseball player. And then finally is Gregory Connolly, who is a professor of the practice of public health at Harvard University. I again thank all of you for being here today. Try to keep the comments to 5 minutes. Your statement becomes part of the record. Of course, you can submit additional written statements or comments if you will after you leave here today.

So I will start with Mr. Von Behrens. I hope I am pronouncing

that correctly.

STATEMENTS OF GRUEN VON BEHRENS, STEWARDSON, ILLINOIS; ROBERT D. MANFRED, JR., EXECUTIVE VICE PRESIDENT, LABOR RELATIONS AND HUMAN RESOURCES, MAJOR LEAGUE BASEBALL; DAVID PROUTY, J.D., CHIEF LABOR COUNSEL, MAJOR LEAGUE BASEBALL PLAYERS ASSOCIATION; JOSEPH HENRY "JOE" GARAGIOLA, SR., MAJOR LEAGUE BASEBALL ANNOUNCER, FORMER MAJOR LEAGUE BASEBALL PLAYER; AND GREGORY CONNOLLY, M.P.H., D.M.D., PROFESSOR OF THE PRACTICE OF PUBLIC HEALTH, HARVARD UNIVERSITY

STATEMENT OF GRUEN VON BEHRENS

Mr. Von Behrens. That is correct, and thank you for allowing me to be here today. I appreciate the opportunity and I really hope that this message I bring to you will make you all a lot smarter on about what tobacco can do to you.

My name is Gruen Von Behrens and I am a national spokesperson here today on behalf of Oral Health America and NSTEP and also myself. I travel throughout the United States as a motivational speaker to youth about the dangers of tobacco use. I have currently been in 46 of the 50 States of America, every province of Canada and spoke to over 2 million kids across North America about this topic. I work with different collegiate and minor league athletic programs. I work with different media across the United States. So I have a lot to say when it comes to this topic.

Now, first things first. I always apologize to my viewers because I understand I can be kind of hard to understand. I have had 34 surgeries to my mouth and to my neck to get rid of the cancer I had. And not everything I say always comes out the way I want

it to, so I apologize to the panel.

Nobody tells me that I have to do this. I didn't get in trouble in my home State of Illinois and they are like, all right, Gruen, for your punishment, you have to go out in public, show people your face and tell them that tobacco did that to you. That is not the reason I do this. I don't do this as an authority figure as somebody who is going to preach to anybody for using a tobacco product because me as an ex-tobacco user realizes how powerful the addiction is on its victims. I am not out there knocking cigarettes out of people's hands and I am not knocking two hands out of their back pockets. I want people to have a fair choice with their life. I want my viewers to be able to look at my face and to my words and my story, understand what I have been through so they can make an educated and thoughtful choice for themselves about whether or not they want to take up this position or not.

I come from a very small town in the Midwest, 750 people in my hometown, and that is counting farm animals and small dogs so it is a very rural area, and as a part of the culture of our area, we use tobacco. My grandfather used tobacco. My uncle used tobacco. Why do these two men who loved me dearly and helped bring me up offer me a product that could hurt me this bad? So I was very naive that this could happen to me. And I hope that by traveling around the country and educating youth about the dangers of tobacco, not only youth but parents, certain forms of government, all different forms. You know, we are sitting here with Major League Baseball and I think it is great to be part of baseball. I think that as a baseball player growing up, and I idolized the people I was watching on TV and that led a small part to my tobacco use but not to the main reason why I used tobacco. Across the United States there is a culture out there where people pick up these habits at a very young age because just being naive to what this product can do to you. The amount of kids and people that I see victimized by this drug is phenomenal. You know, I see 8-year-old kids using spit tobacco. I see mothers wiping their babies' gums with spit tobacco wrapped in a nylon stocking to cure a toothache. I see 10-, 11- and 12-year-old kids coming up to me after my presentation and handing me their chew and saying I don't want to use this no more because I didn't know that that could do that to me.

As I said, I really appreciate the opportunity to be here today. I hope that this message brought to America can educate them about the dangers of tobacco. I see our government sometimes almost telling us that spit tobacco is a safer alternative to cigarettes, and numerous States, they raised the taxation on cigarette sales but they will not raise the taxation on tobacco sales. So as a whole, is that them telling us that this is a safer alternative when I know it is not? Every bit of spit tobacco that somebody puts in their lip, into their oral cavity has the same cancer-causing ingredients in it as three to five cigarettes smoked. So they are hurting their oral

cavity. This is as bad as whether they would be if they ingested a cigarette. And then we talk about harm reduction. Harm reduction. I laugh at the face of harm reduction, guys. You get lung cancer, you get oral cancer. What is the difference? You have still got cancer. You still have a very deadly disease that you have to fight for your life to fix.

I stared using tobacco at the age of 13. At 17 I was diagnosed with a full-blown oral cancer. So often people come up to me and say oh, Gruen, spit tobacco only hurts the person using it. I wish each and every one of you in here who are interested, seriously interested in this cause, to have been with me the day that my mom found out I was sick, the day my mom sat in that doctor's office with me and bawled her eyes out because her son had been diagnosed with this disease because of trickery and misconception that this thing was a safe thing to do, and the impact that had on my mother—I mean, I had people come up and say to me that it only affects the person using it. That is not right. It affects everybody in the community. It affects each and every one of us. People are getting sick from this. As the government, do what it takes to fix this problem. I don't care if it baseball. I don't care if it with health care. Mr. Barton says this isn't a very important thing, we ought to worry about health care. I think we are worrying about health care, guys. We are starting on this level. All right? Let us make it this level.

Thank you for your time. I appreciate the opportunity to be here. [The prepared statement of Mr. Von Behrens follows:]

Statement of

GRUEN VON BEHRENS Stewardson, IL

Hearing: Health Subcommittee, House Energy and Commerce Committee "Smokeless Tobacco: Impact on the Health of our Nation's Youth and Use in Major League Baseball"

April 14, 2010

Chairman Pallone and distinguished Members of the House Energy and

Commerce Health Subcommittee, good morning. My name is Gruen Von Behrens, and I
am a resident of Stewardson, IL. I am a survivor of oral cancer from smokeless tobacco
use, and I travel throughout the country speaking to young people about the health risks
of smokeless and spit tobacco use. I serve on the speakers bureau for NSTEP® (the
National Spit Tobacco Education Program) of Oral Health America, a national non-profit
organization dedicated to improving the nation's oral health. I join my colleagues,
including former NSTEP Chairman, Joe Garagiola, in speaking up about the devastating
effect that smokeless tobacco can have.

I wish to thank the Committee for bringing this important, but overlooked health issue to the table. So much attention is paid to the health effects of smoking. Smokeless tobacco is not "harmless" as advertising would have you believe. It has ruined my life. I am 32-years-old, and I have experienced 34 surgeries, including one radical surgery that removed half of my neck muscles, lymph nodes and a third of my tongue.

I first tried smokeless tobacco at age 13 to "fit in" on a camping trip. I grew up in a rural farming community where smokeless tobacco use is everywhere. My first experience with smokeless tobacco resulted in a powerful addiction that affected my life

in a way I never imagined. Back then, I hit a .400 for the local Comets baseball club, and I wanted to play for the Chicago Cubs when I grew up. Baseball was the center of my world. But as much as I loved baseball, smokeless tobacco was my biggest habit. I had to have it in my lip when I was playing baseball. I liked the way it made me feel and I liked the way it tasted. The risks didn't worry me. We all know that smoking can cause lung cancer, but tobacco advertising fools people into thinking that smokeless tobacco is harmless. It didn't occur to me that I would get cancer—that just happened to old people.

When I was 17-years-old, I was diagnosed with squamous cell carcinoma. The cancer in my mouth spread. Doctors told me there was an 80 percent chance I was going to die. You can not imagine how this news affected my mom. The first surgery lasted 13 hours. This was followed by a painful round of radiation, which finally broke my addiction to smokeless tobacco. After radiation I thought my cancer was over but I had another 33 surgeries to go. Before, there were colleges that were interested in me. But at 17, my baseball days were over.

Anyone who tells you that they can't or won't stop using smokeless tobacco is an addict. I have spoken to professional baseball players who hate the fact that they use it, are scared that what happened to me will happen to them, and still have to fight their addiction. The most important thing we can do is to prevent young people from starting to use, and to help users quit.

I am honored to share my story with you, a story that I have shared with over 2 million youth across the country. Please keep my testimony, and those of others you heard today, close to your hearts as you consider steps to improving America's health. Smokeless tobacco is not harmless, and I ask you to promote smokeless tobacco

education and cessation, encourage policies that limit the ways that tobacco companies reach youth through advertising and promotion of this highly addictive and harmful drug. It is not a safe alternative to smoking.

Thank you for your time.

Mr. PALLONE. Thank you, and let me thank you also. I didn't realize how often you go around and how many States and how much you have become a spokesman for this, and we really appreciate that. Thank you.

Mr. Manfred.

STATEMENT OF ROBERT D. MANFRED, JR.

Mr. Manfred. Chairman Pallone and members of the committee, thank you for the opportunity to be here to address our shared commitment to the reduction of the use of smokeless tobacco products. I would like briefly to review Major League Baseball's past and ongoing efforts to reduce or eliminate the use of such products by players, as well as the legal framework within which Major

League Baseball's efforts have been undertaken.

For almost 2 decades, Major League Baseball has worked on multiple fronts to reduce the use of smokeless tobacco products and educate members of the baseball community accordingly. The centerpiece of our effort is the Minor League Tobacco Policy, which was issued by Commissioner Selig in 1993. That policy bans the use and possession of all tobacco products by club personnel, including players, n minor league ballparks and during team travel. We believe that our efforts at the minor league level are crucial because players must learn at an early age to avoid these product. The minor league policy is displayed in all minor league clubhouses, and each minor league player contract requires the player to represent that he is aware of the policy and agrees to its provisions. To ensure compliance with the policy, Major League Baseball's resident security agents conduct roughly 100 random security inspections of minor league ballparks annually. Players and field managers who violate the policy are subject to game ejection and incur substantial monetary penalties.

Major League Baseball has also administered a formal policy re-

Major League Baseball has also administered a formal policy regarding tobacco products at the major league level for well over a decade. Pursuant to the major league policy, clubs may not permit the distribution of tobacco products in major league clubhouses. The major league policy likewise encourages clubs not to permit club personnel, clubhouse attendants and the like, to buy tobacco

products on behalf of players.

I should also point out that club personnel are barred from smoking when in uniform in view of spectators, and contrary to a suggestion that was made in the earlier panel, our athletes are not allowed to participate in tobacco advertising while in uniform, and I am not aware of a single major league player who endorses tobacco

products publicly.

Our efforts to reduce the use of tobacco products extend beyond formal disciplinary measures and into education and treatment. To that end, the minor league policy encourages field managers to hold tobacco education meetings with their clubs and waives fines for first-time offenders who complete cessation counseling programs that are provided by the club's employee assistance professionals. Major League Baseball has also collaborated extensively with its partners to raise public awareness.

In 1994, Major League Baseball helped establish the National Spit Tobacco Education Program to curb the use of smokeless tobacco products. Major League Baseball has provided NSTEP and its partners with over \$100 million in cash contributions, television exposures and other support to conduct public service activities and announcements, which featured players including stars like Hank Aaron and Derek Jeter.

Within the baseball community, NSTEP has served major and minor league players via numerous education and treatment options. These options include oral examinations, brush biopsies, educational seminars, cessation programs and training for club employee assistance professionals. Through 2003, Major League Baseball, at times on conjunction with the Major League Baseball Players Association, sponsored NSTEP programs with the assistance of grants from not-for-profit organizations including the Robert Wood Johnson Foundation. Clubs continue to administer oral examinations and smokeless tobacco education programs as part of their annual spring training activities. Highmark Blue Cross Blue Shield, the insurance provider for minor league players, also conducts an annual spring training presentation for players that addresses tobacco cessation options.

Largely because of these efforts, the use of smokeless tobacco products has declined substantially in baseball over the last 2 decades. Commissioner Selig nevertheless remains committed to exploring additional opportunities in conjunction with the Safety and Health AdvisoryCommittee, a joint committee of baseball and the MLBPA. Last November, at Commissioner Selig's urging, the committee hosted a presentation on smokeless tobacco use prevention by Dr. Ashok Shaha, a head and neck surgery specialist from Memorial Sloan-Kettering Cancer Center. During the 2010 season, the Commissioner's Office will be surveying players to develop other

educational and treatment programs.

As we carry these initiatives forward, however, it is important for the Committee to bear in mind the legal framework that applies to smokeless tobacco. Like drug testing, the regulation of player use of tobacco products is a mandatory subject of collective bargaining. But unlike performance-enhancing substances, smokeless tobacco products are legal in all 50 States and for sale to and consumption by adults. And even the most ardent critics of smokeless tobacco use as a public health matter would argue that it compromises the competitive integrity of our game in a manner analogous to performance-enhancing substances. While an outright ban on the use of smokeless tobacco in the major leagues is a laudable goal, it will have to be pursued against the backdrop of these legal realities.

I thank you for your time.

[The prepared statement of Mr. Manfred follows:]

STATEMENT OF ROBERT D. MANFRED, JR. BEFORE THE HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON HEALTH, APRIL 14, 2010

Chairman Pallone and members of the Committee, thank you for the opportunity to address our shared commitment to reduce the use of smokeless tobacco products. I would like briefly to review Major League Baseball's past and ongoing efforts to reduce or eliminate the use of such products by players, as well as the legal framework within which Major League Baseball's efforts have been undertaken.

For almost two decades, Major League Baseball has worked on multiple fronts to reduce the use of smokeless tobacco products and educate members of the Baseball community accordingly. The centerpiece of this effort is the Minor League Tobacco Policy, which since 1993 has banned the use and possession of all tobacco products by club personnel – including players – in Minor League ballparks and during team travel. We believe that our efforts at the

Minor League level are crucial so that players learn to avoid these products early in their careers. The Policy is displayed in all Minor League Clubhouses, and each Minor League contract requires the player to represent that he is aware of the Policy and agrees to its provisions. To ensure compliance with the Policy, Major League Baseball's Resident Security Agents conduct roughly one hundred random security inspections of Minor League ballparks annually. Players and field managers who violate the Policy are subject to game ejection and incur substantial monetary fines.

Major League Baseball has also administered a formal policy regarding tobacco products at the Major League level for well over a decade. Pursuant to the Major League policy, Clubs may not permit the distribution of tobacco products in Major League clubhouses. The Major League policy likewise strongly encourages Clubs not to permit Club personnel to buy tobacco products on behalf of other Club personnel, including Players. I

should also point out that Club personnel are barred from smoking when in uniform in view of spectators.

Our efforts to reduce the use of tobacco products extend beyond formal disciplinary measures and into education and treatment. To that end, the Minor League Policy encourages field managers to hold tobacco education meetings with their clubs and waives fines for each first-time offender who completes a cessation counseling program approved by the club's Employee Assistance Professional ("EAP"). Major League Baseball has also collaborated extensively with its partners to raise public awareness. In 1994, Major League Baseball helped establish the National Spit Tobacco Education Program ("NSTEP") to curb the use of smokeless tobacco products. Major League Baseball has provided NSTEP and its partners over \$100 million in cash contributions, television exposure, and other support to conduct public service activities and announcements, which featured Players including Hank Aaron and Derek Jeter.

Within the Baseball community, NSTEP has also served Major and Minor League players via numerous education and treatment options. These options include oral examinations, brush biopsies, educational seminars, cessation programs, and training for Club EAPs. Through 2003, Major League Baseball sponsored NSTEP programs with the assistance of grants from non-profit organizations including the Robert Wood Johnson Foundation. Clubs continue to administer oral examinations and smokeless tobacco education programs as part of their annual Spring Training activities. Highmark Blue Cross Blue Shield, the insurance provider for the Minor League players' medical plan, also conducts an annual Spring Training presentation for players that addresses tobacco cessation options (among other things).

Largely because of these efforts, the use of smokeless tobacco products has declined substantially in the Baseball community over the last two decades. Commissioner Selig

nevertheless remains committed to exploring additional opportunities in conjunction with the Safety and Health Advisory Committee, a joint committee of Baseball and Major League Baseball Players Association representatives. Last November, at Commissioner Selig's urging, the Committee hosted a presentation on smokeless tobacco use prevention by Dr. Ashok Shaha, a head and neck surgery specialist from Memorial Sloan-Kettering Cancer Center. And during the 2010 season, the Commissioner's Office will survey all Minor League players to develop other educational and treatment programs.

As we carry these initiatives forward, however, it is important for this Committee to bear in mind the legal framework that applies to smokeless tobacco. Like drug testing, the regulation of Player use of tobacco products is a mandatory subject of collective bargaining with the Players Association. But unlike performance-enhancing substances, smokeless tobacco products are legal in all fifty states for sale to, and consumption by, adults.

And not even the most ardent critics of smokeless tobacco use as a public health matter would argue that it compromises the competitive integrity of our game in a manner analogous to performance-enhancing substances. While an outright ban on the use of smokeless tobacco in the Major Leagues is a laudable goal, it will have to be pursued against the backdrop of these legal realities.

Thank you again for this opportunity.

Mr. PALLONE. Thank you, Mr. Manfred. Mr. Prouty.

STATEMENT OF DAVID PROUTY

Mr. Prouty. Thank you. Chairman Pallone and members of the committee, thank you for the opportunity to testify today. My name is David Prouty. I am the chief labor counsel for the Major League Baseball Players Association. I won't repeat verbatim my written testimony but I just want to make a few points based on the testimony and also what we have heard today.

First, no one disputes the health risks of smokeless tobacco. You have heard the medical evidence today. You will hear more. And you have heard the compelling testimony of Mr. Von Behrens. The players association completely agrees that smokeless tobacco poses

a huge health problem for this country.

Second, and it is for that reason that the players association has long discouraged its members from using smokeless tobacco. We have participated in educational programs to alert the players and the public to its dangers. For players, we have run educational seminars and offered medical screenings in spring training. We have participated in the NSTEP program that Mr. Manfred referred to, to offer cessation workshops. We have worked with Mr. Garagiola, in fact brought him to address a meeting of our executive board to talk about this topic.

For the public, we have worked again through NSTEP on various outreach programs including the taping of a series of public service announcements involving prominent players including Derek Jeter,

Hank Aaron and also Jeff Bagwell and Alex Rodriguez.

We have also embarked on a new program with the Partnership for a Drug Free America called Healthy Competition, which is focused on helping parents and children make smart decisions regarding health and nutrition. The players want to help kids choose what to do, not just tell them what not to do. Through this program, we hope to educate young people, both athletes and non-athletes, to make smart choices when it comes to fitness, supplements,

drugs, alcohol and tobacco, including smokeless tobacco.

Third, the obvious question, why isn't smokeless tobacco banned in baseball? Remember that smokeless tobacco is a legal product available for all adults to purchase everywhere in the United States but we can and we will educate players as to why they should not use it. There is a tension here because many players do not think they should be banned from using a product which Congress has so far deemed to be legal. If Congress were to ban smokeless tobacco, the players association would not object and might even support such a measure. Would the players association agree to ban smokeless tobacco in baseball as part of our next round collective bargaining negotiations? Well, we are a union. We pride ourselves on having a democratic structure and a democratic process, much like this Congress. It is up to the players, the members of this union, to decide what issues they want to bring to the table. I can guarantee you that I will bring back to the players the concerns that have been raised here today, and I am sure more will be raised, back to the membership of the union and that this issue

will get a full airing. That is how a union works and that is how collective bargaining works.

Lastly, since this is the Health Subcommittee, I want to raise with you another health hazard that affects our members and the public at large, and that is the issue of dietary supplements. Simply put, the existing regulatory scheme is not working. There are many quality products on the market but there are also many that contain dangerous ingredients that aren't labeled as such. In fact, the Food and Drug Administration just released a list of over 100 dietary supplements that can be bought over the counter that contain performance-enhancing substances which are banned under baseball's drug-testing program. Our members have suffered the consequences by testing positive and receiving suspensions as a result of ingesting these products that contain such unlabeled substances. We realize this may be a politically sensitive issue for some on this committee, but without your help, millions of Americans, young and old, athletes and non-athletes, will continue to be at risk from taking supplements that contain steroids, pharmaceuticals and other dangerous substances. We hope that you will give this issue as well the attention that it deserves.

Thank you for your time. I will be happy to answer any questions at the conclusion.

[The prepared statement of Mr. Prouty follows:]

BEFORE THE UNITED STATES

HOUSE OF REPRESENTATIVES

COMMITTEE ON ENERGY AND COMMERCE SUBCOMMITEE ON HEALTH

STATEMENT OF DAVID PROUTY
CHIEF LABOR COUNSEL
MAJOR LEAGUE BASEBALL PLAYERS
ASSOCIATION

APRIL 14, 2010

Mr. Chairman and Members of the Committee:

My name is David Prouty, and I serve as the Chief Labor Counsel of the Major League Baseball Players Association. Thank you for the opportunity to testify today about smokeless tobacco products and their use by major league baseball players.

There is no doubt that smokeless tobacco products are dangerous, and that the long-term use of chewing tobacco and other smokeless tobacco products can cause serious health problems. These products are addictive. They greatly increase the risk of cancer, including esophageal and oral cancer, and cancers in the mouth, throat, cheek, gums, lips and tongue. It is impossible to listen to or read Mr. Von Behrens' testimony and not appreciate just how dangerous these products can be.

For these reasons, the Players Association has long discouraged its members, and everyone else, from using smokeless products. We have worked with Major League Baseball to educate players about the realities and consequences of using smokeless tobacco products.

As Mr. Manfred indicates in his testimony, Major League Baseball created the National Spit Tobacco Education Program (NSTEP) in 1994. The program's purpose was to encourage both players and the public not to start using smokeless tobacco products, to help those already using these products to quit, and to help educate all Americans on the dangers of smokeless tobacco.

The first chair of this program was Joe Garagiola, a well-respected former player and nationally respected broadcaster and someone with whom we worked in the effort to educate players about the dangers associated with the use of smokeless tobacco. Additionally, over the years, current and former players, including Derek Jeter, Henry Aaron, Jeff Bagwell and Alex Rodriguez, have assisted with a variety of educational efforts sponsored by NSTEP. In addition, in 2000 and 2001, Major League Baseball and the Association worked together to give smokeless tobacco special emphasis during spring training. Under the leadership of NSTEP, we held educational seminars, oral medical exams, and developed cessation programs that highlighted the addictive nature of these products.

As some of the members of this subcommittee know, each year we meet with every member of the Players Association during spring training to discuss a variety of issues of importance to the membership. Topics range from the state of collective bargaining, to issues involving competition and rules changes, to

developments concerning health issues, including smokeless tobacco. As you can expect, the subjects we discuss vary from club to club.

Over the last few years, much of the discussion in these meetings has focused on our drug testing program, and the ongoing changes we have made in its operation and administration, but through the leadership of our new Executive Director Michael Weiner, we have already begun working with the Partnership for a Drug Free America on a new program we call Healthy Competition. The purpose of the program is to begin to address the difficulties in getting both parents and children to focus on how to make good choices our health and nutrition. Our members understand that it is not enough simply to say to young people "do not do this" or "do not take that." Such advice begs the question of what one should do. Consequently, we are working with the Partnership on the development of a variety of different educational materials utilizing different mediums to explain how we all can do a better job of making the right choice when it comes to fitness, exercise, dietary supplements, drugs, alcohol and tobacco. Obviously, educating young people, especially young athletes, about the dangers of smokeless tobacco products is a key component of this effort.

I realize there are some who believe that the key to eradicating the use of smokeless tobacco products is to ban their use by baseball players during games or

in the clubhouse. After all, it is argued, baseball has banned smoking of cigarettes during games and in the clubhouse. We respectfully disagree.

First, we believe baseball players should not be prohibited from using substances that are perfectly legal and available to the general public. Congress and the federal government are the ultimate arbiters of what products may be consumed or used by the adults, regardless of their wealth or celebrity. Should Congress in its ultimate wisdom decide that smokeless tobacco should be banned, the MLBPA would not oppose that effort, and might very well support it.

Reaction among our members would undoubtedly be similar to the reaction in the general public. Many would applaud the decision. Some would oppose it.

Second, on a practical level, the use of smokeless tobacco is not the same as the use of cigarettes. Cigarettes impact the ability to play the game, are banned from public use under a variety of state and municipal laws, and may endanger the health of those in the immediate area.

Third, there are a variety of smokeless tobacco products that can be used without any of the telltale signs normally associated with the use of chewing tobacco. In fact, it would be impossible for fans either at the stadium or watching on television to know whether a player was using one of them. Our objective, however, is not to hide the use of smokeless tobacco but to convince players

through education that it is in their long term interest to stop using any tobacco products, visible or not, both at work and at home. But until a player reaches that decision, we do not believe he should be banned from using products Congress has thus far concluded may be used by all other adults.

I would be remiss if I did not use this opportunity to raise, once again, another problem of singular concern to our Association. As our Executive Director noted in his testimony last November before the Subcommittee on Commerce, Trade, and Consumer Protection and, as our former Executive Director noted in a series of letters to members of the full Committee last year, the current regulatory scheme for dietary supplements is not working.

Nearly half of all Americans claim to use supplements, many on a daily basis. Those individuals are worthy of the same basic protection promised those who consume traditional food – the assurance that the products regulated by the FDA, that are sold without restriction throughout the country to adults and children, are safe and that the products' labels can be trusted.

There are many reputable supplement manufacturers who provide quality products but, unfortunately, our country is still awash with supplements that contain pharmaceuticals and other dangerous ingredients. In many instances, there is no indication on the label of products sold on the shelves of national chain

nutrition stores that indicate what is really inside the bottle. There is no warning that the supplement may contain substances prohibited by the FDA which also happen to be banned under our drug testing program. Indeed, members of our union have suffered the consequences of positive tests and the resultant suspensions under just such circumstances.

The MLBPA has done what it can to advise our members when we become aware of such dangerous supplements and the substances they contain but, as a private organization, we are limited in what we can by ourselves. We believe a broader effort is necessary if this problem is to be effectively curtailed. Until that happens, countless Americans of all ages, athletes and non-athletes, will be misled about what is inside the supplement products they are taking. It is has been over a year since we first raised this problem with the Committee and asked for assistance. We hope you will find time to give this matter the attention it deserves.

Again, thank you Mr. Chairman. I appreciate the opportunity to testify, and I look forward to answering any questions you may have.

Mr. PALLONE. Thank you.

Mr. Garagiola.

STATEMENT OF JOSEPH HENRY "JOE" GARAGIOLA, SR.

Mr. GARAGIOLA. Thank you, Chairman and the committee and——

Mr. PALLONE. I think your mic, you have to bring it closer and—there we go.

Mr. GARAGIOLA. I have never been around a microphone before.

I don't know what to do. I just holler.

You are not going to hear a bunch of numbers from me, and don't start the clock yet because I have got all kind of notes here on my papers. These guys come with typewritten sheets and all that, but I made some notes are listening to this. Six hundred and fifty million dollars, when we started out with—and I hate to hear that word "smokeless." That belongs to the tobacco companies. I could use a word that would get me kicked out of a game when I hear that, but I will not. I watched 60 Minutes like you did and it was scary.

Let me just throw a few things out. In 1993—and I keep hearing numbers and it is true. In 1993, 21 percent of the players in the World Series used tobacco, spit tobacco. That is what I call it, spit tobacco. That is what it is. In 2000, 7 years later, it was zero. Why was that? I was in the trenches with a bunch of guys who went with me, and I called the producers. I said why do you guys stay on that shot, get off that shot. I called the guys who—the presidents of the networks. Lenny Dykstra, who was the poster boy, just to give you a story, I went up to him and I said Lenny, why do you use that garbage, what did they give you? Did they give you any money? He said no, I have to have it. Why do you have to it? I just have to have it. And I said just tell me you won't use it during the World Series. I will talk to my guys at CBS and we will make an impact. No, I can't do that. Lenny Dykstra has quit using it, guys, because he ran into a problem. So I don't know about numbers and all that kind of stuff but I just want you to know that that is where it got started.

Six hundred and fifty million dollars—when I was with NSTEP, I made speeches across this country. I will never forget going into Connecticut with the attorney general, and that is when the tobacco company, they were going to use it as a safe alternative to cigarettes. Oh, come on. Give me a break. I am not going to go through all this. I am just going to tell you some of the things that I have learned.

In my day, we called it chew. I chewed. Why did I chew? Because the others players chewed. I thought it was part of baseball, and that is what it is all about. I mean, the things that you do because the other guys do it. They used to give us salt tablets. Salt tablets, they used to give us. I think they were trying to kill us is what I thought they were trying to do. But it has improved so much, and now, I got so much I want to say I am choking on myself.

Like many other players, I thought being a major league player, you had to chew. You watch those guys, Lon Warnicke, who I grew up with, that kind of—I chewed until my daughter came home from school one day and said Daddy, are you going to die? I said

sweetheart, sure I am going to die, we are all going to have to die. She said I mean are you going to die. I said yes, but not now. I am not looking forward to it. And she said no, and she had that look in her eyes. And I said sweetheart, why are you asking me? And she said because we're studying about tobacco and we are studying about lungs and they said if you use tobacco you are going to die. I stopped. I stopped. I wish you guys could walk with me on a field because I have been called everything from a Nazi antitobacco chew zealot. I mean, come on. This is what these ballplayers do. I mean, forget the numbers and all that. Get in the trenches and watch them. And with the minor leaguers, baseball has done a great job, and baseball is taking a beating here. They really have, and I am sitting next to the guy that I wanted to romance here, put some Chapstick on and get him to do the job. But to me, in my 20 years of working to spread the word about the dangers of smokeless tobacco, many of my friends, Jack Crowl, a coach, he lost half his tongue like my friend Gruen. I have a tape here, and I am all over the place I know. I am going to tell you about this tape. This is Gruen Von Behrens' tape, and if any of the people on the committee would like to have a copy, we will get it to you. I will get it to you. The Diamondbacks paid for this. We didn't have any of that 650 million. There is a booklet that Bud Selig, the commissioner, gave out to people, and I mean, it is nothing but little cartoons that kids can see. Here is one. It is easy to quit smoking cigarettes, you just take them out of your mouth. No, Daddy, let us make him a nonsmoker—he is working on a snowman—he will last longer. I mean, I was begging everybody to help us, and they did. But I lost Jack Crowl, lost part of his tongue, couldn't talk, and in a year he was dead. Bill Tuttle—Bill Tuttle died one piece at a time. Bob Leslie, a high school coach—and I never asked anybody to make a tape or a DVD. Bob Leslie called and he said Amy and I, we want to make a tape, and we went out there and made this tape, and I will never forget when Bob Leslie died, I spoke at his funeral, and here was Amy right where that chair is, the second chair, holding a baby, and I said to myself, in her 20s, holding a baby that can't even stand up by himself or walk, she should be enjoying it, and instead of being a mother and a wife, she is a widow. She hadn't even seen 30 years old. They all died too soon. That lit the fire, guys. I want to tell you, that lit the fire, and that is why I agreed—in 1994, that is how long I have been going

out there—and I never got paid a nickel. Never got paid a nickel. I didn't want to get paid. If they wanted to hear my speech, they had to pay my flight there, and I am going to tell you, sitting in the middle seat sucks. That is not in the script, by the way. But anyhow, I agreed to chair the National Spit Tobacco Education Program, and we had some money from the Robert Wood Johnson Foundation. I worked with them and now I haven't heard from

anybody. It is almost like I got leprosy.

Anyhow, I lobbied Major League Baseball to ban the distribution of tobacco products in major league clubhouses, a rule that is still in effect, and I am going to tell how that started. Rob knows it. I went to the Diamondbacks and I said to them, you guys hired the clubhouse guy, tell him he can't put that tobacco there and don't let the tobacco companies give you free tobacco, and kind of looked at me and he said what do you mean. I mean clean it out, let them stop, make it inconvenient to buy the tobacco, which they did, and that was good. But you know what? When the kid comes up from the minor leagues, he knows he shouldn't use it but I see it. The first thing they know, they don't even pick the bat first, they throw a chew in their mouth. We have to educate, educate, educate, and Commissioner Selig is behind it 100 percent.

Hey, U.S. tobacco, if you look at it, they don't call themselves a U.S. tobacco company anymore, they are a U.S. smokeless tobacco company. Now, if that isn't a subtle commercial, I don't know what

is.

I have letters from Commissioner Selig and Donald Fehr both who are backing what I am doing. Why can't baseball and the players association right here get together and ban it? Take it off the field. I think it was Mr. Waxman who said something about we don't see a player going out there with a cigarette in his hand. I know where he got that line, when I testified before his committee. I mean, Arnold Palmer used to play golf, walk on the green, flip a cigarette and putt, but we don't have that in baseball. Tobacco is tobacco is tobacco. Get together. The players association, baseball, get together, guys, ban tobacco and anyone who uses it is penalized. I don't care if it is a suspension. I don't care if it is fines or what. Get it out of our game. It is a great game, greatest game going. I have heard all kinds of things about it.

I almost forgot the most important thing. We have a club in Arizona that I went to the Diamondbacks and I said you know, why don't we let the kids in free. I wanted to call it Let's Kick Their Cans, and this is what Bill Keane did for me. We call it the No Chew Crew, and they get a red tee shirt with No Crew Chew and they sign a pledge that they are not going to use tobacco. Well, you don't know if they are going to use it or not but they are going to be aware of it, but they get into the game free if they come chap-

eroned.

This is Gruen Von Behrens' tape. We got this in every school in Phoenix, Arizona. How I would love to see that in every school in

Arizona, the whole State.

Spit tobacco. I would like the players—and boy, do I get it from them—who are role models, and I don't care what anybody says, whether they agree, Charles Barkley notwithstanding, they are role models. I want them to quit carrying a can of dip in their uniform pockets and especially where the youngsters see them. I just had an incident last Saturday. I did a broadcast. I am just getting out of surgery. I had three major surgeries. I didn't work at all last year and I was in the hospital all of 2009, but when I got this invitation, that is how important this is to me. I was in the Diamondback clubhouse and one of the players, I don't want to name him, he is sitting there with a laptop and he is dipping. I go around the corner and they got a kitchen now. We never had a kitchen. If you had a bologna sandwich, you were lucky. These guys sit there and watch Days of Our Lives or whatever instead of taking batting practice and then they wonder why they can't hit and they are going to be broadcasters. I saw him using that stuff. I said why are you using it now? Oh, it feels good. Until they find something. I can name players. Curt Schilling, we took him in for a brush biopsy

that Rob was talking about. He came out, he was as white as this towel because they found a lesion and he had to have it biopsied. Curt Schilling, who pitched in the World Series, I don't know if he's using again. He may or may not. But it is a deadly, addictive habit, and it is an uphill battle, this spit tobacco, and I am going to tell

you why. Nobody has mentioned it, but I will.

I have made speeches before the firefighters, police officers, anyone who works with the public, they can't smoke. They can't smoke. So what do they do? They use spit tobacco. And when I told them about it and the reaction that I got was tremendous, and they start early because the tobacco companies advertise to them at a very early age. These companies mislead you. You want to talk about advertising? Here is a catalog that they put out, OK? I know you have got a bunch of books there, Chairman. I will give you this if you want it. In fact, one of them got me mad. Brad Roudeaux—Brad Roudeaux is from the University of Alabama Birmingham. He is on the payroll of the tobacco companies. So if you want to burn it, you can burn it. You have my permission. Here is a catalog of gifts. Here is a pool table. Do you know how many lids you need to get this pool table? Ten thousand lids. You use 10,000 cans of tobacco, you would have cancer of the feet. And, you know, they talk about cowboys and westerns and all that. They do that.

We were at a NASCAR—one of the people here talked about NASCAR. I went there and we put a sign up there, smokeless does not mean harmless. They came and said that it was insulting to them. I said insulting? I can't believe it. They made us take it

down.

It is not a safe alternative to cigarettes. Fewer people die from it. That is the song of the tobacco companies. You know what it is like? And this is what I said to the attorney general in Connecticut. It is like saying don't jump out at the 50th floor, what are you nuts? Jump out of the 30th floor. You got 20 floors on your side. The result is going to be the same. It is a dangerous, deadly habit and baseball can't solve the problem by itself. We need help. The players association—Commissioner Selig encourages everything that I do. Donald Fehr, he is gone now, right?

Mr. Prouty. Still around but he is retired.

Mr. GARAGIOLA. But you are here.

Mr. Prouty. I am here.

Mr. GARAGIOLA. OK. You go back with this message.

Let me just say this. We need truth in advertising. That is important. I can't think of the Congressman's name, he was from California. He called me and he said he is going to have a press conference in California and could I get a ballplayer because he wants to have stronger words on the can, and I wasn't too smooth with him and I said is this a photo op or do you really mean. He said no, I am really going to do it, and I said what are you going to do. He said make a stronger message black print, big print. I said OK. We came out there. A kid named Mike Watson from Denver, he is a firefighter now, kid was on a Friday, he quit. Monday he went back to using it. And, you know, what can I tell you? Smokeless does not mean harmless.

I don't know what my time is but I am very emotional about this——

Mr. PALLONE. Your time is up but we appreciate the fact that

Mr. GARAGIOLA. Thank you very much.
[The prepared statement of Mr. Garagiola follows:]

STATEMENT OF JOE GARAGIOLA BEFORE THE HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON HEALTH, APRIL 14, 2010

Good morning, Chairman Pallone and members of the Committee. Thank you for letting me participate in this important discussion about the dangers of smokeless tobacco products. Smokeless doesn't mean harmless. In my day, we called it chew. Like many generations of Major League baseball players, I started using spit tobacco because I saw other players doing it and I thought it was part of being a Major League player. I chewed during my playing career, and I did not quit until my daughter saw a presentation about the dangers of tobacco in elementary school and begged me to stop. I am so grateful to my daughter for saving me from the pain and suffering that I would have risked if I had continued my habit.

But in my twenty-years-plus working to spread public awareness about the dangers of smokeless tobacco products, many former Major League coaches and players -- like my friends Jack Krol and Bill Tuttle -- died too soon. Their stories and their loved ones "lit the fire" in me to do my part to steer our young people away from this deadly, addictive products.

That is why I agreed, beginning in 1994, to chair the National Spit Tobacco Education Program ("NSTEP"). Through the years, I have worked with NSTEP to raise public awareness and encourage early diagnosis of tobacco-related health problems. I lobbied Major League Baseball to ban the distribution of tobacco products in Major League clubhouses, a rule that is still in effect today. I continue to encourage Major League Clubs to raise public awareness through activities like the "No Chew Crew," a youth club sponsored by the Arizona Diamondbacks that has gotten over twenty thousand

children in the Phoenix area to pledge not to use spit tobacco. And I have spent countless hours urging Major League and minor league players to stay away from smokeless tobacco – or as I call it, spit tobacco. Calling it smokeless tobacco is a subtle commercial: it is spit tobacco.

Of course, I continue to urge Baseball to do more. I would like to see the Major League players agree to the terms of the Minor League Tobacco Policy, which bans Club personnel from using and possessing tobacco products in ballparks and during team travel. I would like the players — who are role models — to quit carrying cans of dip in their uniform pockets, where especially the youngsters can see them. Even more can be done to educate young players about the facts and images of spit tobacco.

But in the bigger picture, this is an uphill battle because smokeless tobacco is not just a baseball problem; it is a problem for all of society. Many ballplayers are addicted to smokeless tobacco, but so are many people from other walks of life – Wall Street executives, firefighters, and police officers. They start early because tobacco companies advertise to them at an early age, and they do not tell the truth. These companies mislead our young people – future ballplayers, but also future lawyers and future bankers – to believe that smokeless tobacco is a safe alternative to cigarettes. It is not. "Fewer people die from it" is the song of the tobacco companies. It's like saying don't jump out of the 50th floor; jump out of the 30th floor. You've got twenty floors to your benefit but the answer is the same. This is a dangerous, deadly habit, and Baseball cannot solve the problem by itself. We need make sure the tobacco companies do not target our young people. We need truth in advertising and stronger warnings on packages. They need to realize that smokeless is not harmless.

I thank the Committee for focusing its attention today on this very important issue. We need help.

Mr. PALLONE. No, I appreciate that you spent so many years dealing with this and trying to make a difference, and I know you are making a difference, so thanks a lot, really. I appreciate it.

We will go to Dr. Connolly.

STATEMENT OF GREGORY CONNOLLY

Mr. CONNOLLY. Thank you very much. It is really hard playing

cleanup witness to Joe Garagiola, believe me.

I did have the opportunity to testify 25 years ago before Mr. Waxman on this very issue, and I think the only difference I can see is that at the time Mr. Waxman had no hair and I did have hair.

I am a dentist. I teach at Harvard. I had the opportunity to work with Major League Baseball Players Association for spring training and conducted surveys on why they used the product, also did examinations of the oral cavities.

I just want to go through with what the players risk. If I represented a union, I would be concerned with the health of my union members. The Teamsters put efforts into protecting the health of their union members and I think other unions in the United States of America should worry about their union members.

[Slide shown.]

But just turning over here, if you take the dip out you see something called leukoplakia. This is a grade III, and I used to have a game with the Blue Jays, I can guess how many dips you use a week game. Just by looking at these lesions, you can identify is it one can, two cans, three cans, four cans. And I remember one player said I beat you, doc. I said one can. I said look over here. It was two cans here and two cans here. The University of San Francisco screened 52 players and found two precancerous lesions in those white lesions, and those are precursors to cancer. They are present in about 50 percent of the players. The players tell me they want to stop, they can't because they are addicted and they are doing it in spite of a known health problem.

[Slide shown.]

This is another famous baseball player who spent literally \$10,000 to treat another condition. This is where the nicotine and the ingredients get in and destroy the bone tissue. He had to have grafting, and unfortunately midlevel of the season he is back using again. Next slide, please.

[Slide shown.]

This is use rates. We monitor use rates over time, and we see about one-third of the players use it, minor leaguers less, maybe because of the ban with minor leaguers. I am really not sure. But this really hasn't changed. So we are still seeing players at risk of developing disease not during their careers in baseball but most likely later in baseball. And I think you have to protect the health of the players. That is the basic element here. Next set of slides, please.

[Slide shown.]

So then we also look at reasons why the players use it, and I asked them. We did a survey among 556 players and the respondents who were heavier users primarily used reasons for addiction. It was for, "I was hooked," "I was treating relaxation, withdrawal."

Not one player said I used it to enhance my performance. Players are not proud of using this, and that is the reality. They wish they didn't start as Little Leaguers or as high school ballplayers or as minor league ballplayers. Next slide, please.

[Slide shown.]

We estimated use over time, and it has been about 9 minutes of game use from 1987, 1986 to 2004. It hasn't changed. What has changed is the use now is being concentrated by a handful of players. It is only one or two. The vast majority of baseball players do not want to be bad role models, and the only way one is going to deal with those one or two players, and I can just look at-you know, we banned advertising through the MSA. We banned it through the FDA Act. But all you have to do is pick up the front of Sports Illustrated, and fortunately this guy is wearing a Dodgers uniform and not a Red Sox uniform, to see what type of advertising reaches kids across America. I told the Jays, I said, you know, based on the use you used just in the World Series, that equals the salary of the entire club, and you guys are deemed to be greedy by Americans. The one guy got up and said I am going to call my agent. And it is spreading. This is Facebook. We are seeing dozens and dozens of groups on Facebook with high schoolers extolling the virtues of using smokeless tobacco products, and it is all related to Major League Baseball players. We see two groups on steroids, one opposed and one saying maybe it is OK, but we are seeing widespread use of adding a drug, nicotine, to users. Next slide, please. [Slide shown.]

You know, when we take an oath as health professionals, we take an oath to do no harm. That is called the Hippocratic Oath. It is not an oath to do less harm. I want to make that perfectly clear. We take an oath to do no harm. We have medications called Nicorette that are outselling these newer products 1,000 to one. They are being used effectively. They are approved by the FDA. They increase quit rates. They double quit rates and they don't have cancer-causing chemicals in them. We have tens of thousands of baseball fields across this Nation and it is banned on virtually every one except 30 yet those 30 fields are the most important fields to the health of American children, only those 30. You can't dip in high school. We got NCAA to stop it. Major League Baseball stepped to the plate and stopped it, and we have a problem right now in America. We have a problem in America, and that is protecting the health of the union and letting the members do what they want to do and not be victimized by one or two players who think somehow it is glamorous to throw it in your mouth and look like who knows what.

I want to thank you very much for giving me the time to testify, and the last time I was with Joe was at the Red Sox game where he announced the whole gang to me and my son. It was a wonderful experience. Thank you, Mr. Chairman.

Mr. GARAGIOLA. No spit tobacco, either.
[The prepared statement of Mr. Connolly follows:]

Testimony Before Committee on Health and the Environment On the Public Health Effects of Smokeless Tobacco

Gregory N. Connolly, D.M.D., M.P.H.
Professor
Harvard School of Public Health

April 14, 2010

Background and Qualifications

My name is Gregory Connolly. I am a professor of public health practice at the Harvard School of Public Health and a dentist. I have conducted research and educational programs on smokeless tobacco use for over 20 years including spending three Spring Trainings in Florida surveying players on use, screening oral lesions and providing counseling on how to quit. In collaboration with the Professional Baseball Players Training Association, we developed a self-help quit guide for athletes on quitting smokeless use which was later used at high school, college and professional baseball team levels.²

I and others have also conducted research on the impact that public use of smokeless tobacco by Major League Baseball (MLB) players has on youth exposure to messages about the use of smokeless tobacco and its free advertising value. 3,4,5 I have also worked with the NCAA and MLB on developing and implementing policies that prohibit use by college and minor league players while on the field.

My testimony will review the health effects of smokeless tobacco, the use by MLB players, reasons for use, and youth exposure to use based on televised World Series Games from 1988 to 2005.

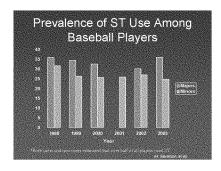
Health Effects of Smokeless Tobacco on Major League Baseball Players

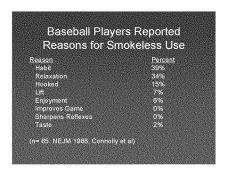
Smokeless tobacco (SLT) causes disease including nicotine addiction, oral and pancreatic cancer, periodontal disease and possible unknown systemic disease associated with toxic compounds such as tobacco specific nitrosamines, benzopyrenes and heavy metals. ^{6,7}

Use of Smokeless Tobacco by Major League Players

There has been traditional use of chewing tobacco by a few players since the game was first invented. But, today chewing tobacco has been replaced by moist snuff, a finely ground tobacco placed as a dip between the check and gum. This form of SLT is highly addictive and causes serious health problems. Its introduction into baseball was only a few decades ago and a direct result of heavy sports marketing by the tobacco industry. Regretfully, the practice rapidly spread throughout baseball but is a relatively new phenomenon which should be eliminated. Presently, use of SLT is banned from every baseball field in America, Little League, Babe Ruth and NCAA and the Minors. There are only 30 baseball fields which use is unrestricted and they are the most important to American youth.

Baseball players are at major risk of this disease because of their high level of use whether it be in high school or as professional ball players. ^{1,9,10,11} Both my and other research has found that about one third of major league players report using SLT, in particular, moist snuff and one quarter of minor leaguers. The lower rate among the minors could be due to the ban on use in 1993.



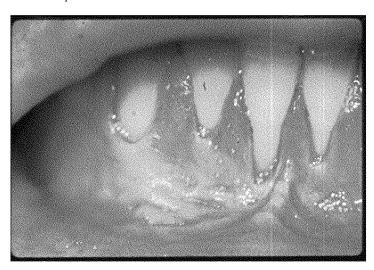


Players primarily use smokeless to bacco because of its drug effects that cause dependence or addiction and players do not report that use enhances performance or ability. $^{1.8}$

Finally, the vast majority of players want to quit and seek assistance to do so.¹ Below are some of the examples of the clinical effects of smokeless tobacco use on player's health that I have seen during Spring Training sessions.



Oral Leukoplakia



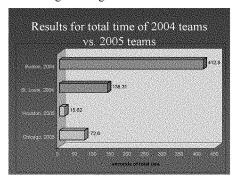
Periodontal Disease and Leukoplakia

<u>Use of Smokeless Tobacco (SLT) by Players is Heavily Seen by Children and Contributes to Their Use of SLt</u>

The use of SLT by players has a powerful role model effect on youth particularly among young males in sport, some of whom ironically remain addicted in future careers as professional athletes. From 1988-2005, we and others have studied televised use of SLT during selected games of the World Series and on average, we observe from 24 to two minutes of use with an average of nine minutes per game. 3,4,5

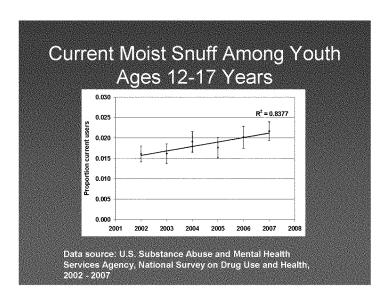
	Trends of World Series ST Use		
ear	Teams	Total Perceptible Use (minutes)	Researcher
986	Mets vs. Red Sox	23.9	Jones
987	Cardinals vs. Twins	11.8	Iones
988	Dodgers vs. A's	7.8	Sussman and Barovich
1989	Giants vs. A's	7.7	Jones
1990	Reds vs. A's	7.3	Jones
1991	Braves vs. Twins	9.3	Jones
992	Braves vs. Jays	3.5	Jones
1993	Phillies vs. Jays	20.8	Tones
004	Cardinals vs. Red Sox	5.2	Johnson and Rothman
2005	Astros vs. White Sox	1.5	Caughey and Tejani

The televised value of just one game is on average worth millions of dollars in free advertising reaching millions of adolescents.



Extrapolate the advertising over a season; the free advertising value to the manufacturers of SLT is probably worth more than the combined salaries of all MLB players combined.

There can be no doubt that public use by MLB players directly contributes to youth smokeless tobacco use in the U.S. Of major concern is that SLT use is increasing 5% per year nationally and among adolescent males, ages 12-17, has increased 25% from 2004-2008. This group only shows a significant increase in use.



Another major concern is the spread of messages about MLB baseball players through internet social networking sites visited by teenagers on sites such as Facebook. We found many groups on Facebook dedicated to MLB players using smokeless tobacco with a total of thousands of members all extolling the virtues of SLT use. This is alarming. Below are typical list of quotes from this site.

Quotes from Facebook, Baseball and Chew Clubs

Nick: "yo who saw the game 4 of the yank and indians....towards the end the camera guy had damon and jeter...and all u see is damon gettin rid of his bomb..lol"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541

[Accessed 4/12/2010]

Matthew: "nothing like a nice fat lip when your playing baseball" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Joe: "Dustin Pedroia packs bombs, so does Youlk they are probaly 2 of the biggest up and coming stars of the red sox"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

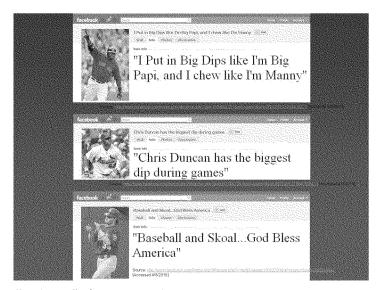
Todd: "man threw in my first roofer when i was 11. the best stuff is citris with big league chew or theres always copenhagen with a bit of whisk."

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

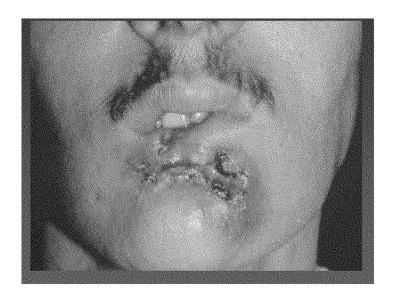
Travis: "The bigger the dip, the better he plays!!"

Source: http://www.facebook.com/group.php?v=wall&ref=search&gid=2317662091

[Accessed 4/12/2010]



(See Appendix for more quotes)



Oral Carcinoma at the Site of SLT Placement

Smokeless Tobacco Use is Incompatible with the Mission of Professional Baseball

Sport is the vehicle by which we pass values down to the young, how to compete, respect your fellow man, and accept winning or losing graciously, but most of all value personal health and fitness. When a professional baseball player uses SLT, condoned by MLB, we do not pass values down, only the potential for future addiction. Leadership is needed now by both the Players Association and MLB to protect not their own interests but the interests of American youth and become true health players for America.

Major League Baseball and the Players are Expecting A Ban on Use and are Ready for It A major finding from our research is that public use of SLT is declining, but still is unacceptably high. It is being confined to fewer athletes today than 20 years ago. For unknown reasons, these athletes are more heavily using the product and they account for

the bulk of televised exposure. The television cameras seem to be overly focusing on the use of SLT.

I'd like to end my testimony by showing a one minute video I did a few years ago with ABC news on this problem.

(Show Video)

Conclusion

Based on these observations, I feel strongly that the vast majority of professional athletes do not want to use these products on the field, particularly in front of children, but are addicted and a few unwittingly may believe it makes them more appealing on camera. The majority of players do not use the product and the problem is now among a handful of players that only a complete ban could address. I conclude that the athletes are expecting a ban, like the ban on smoking instituted in the 1950s. It is in the interest of the health of the millions of young boys in Little League, Babe Ruth or High School baseball for MLB and the Players Association to step up to the plate and take a lead on oral cancer prevention as they have for other cancers and prevent not foster disease by stopping SLT use on the field.

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Appendix

Quotes on Facebook

Phil: "Gotta love Swisher tho. I want him to sign my tin and pack one with him" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Elliott: "im a big fan of citrus i dont know what i would do if i didnt have dip during baseball"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Joe: "Dustin Pedroia packs bombs, so does Youlk they are probaly 2 of the biggest up and coming stars of the red sox"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Donny: "i was at a sox game a while ago and got swishers autograph and he didn't spit for like the whole 20 minutes he was signing autographs now thats a champ"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541
[Accessed 4/12/2010]

Todd: "man threw in my first roofer when i was 11. the best stuff is citris with big league chew or theres always copenhagen with a bit of whisk."

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Elliott: "last night my summer team was sitting around in a hotel and 2 kids put in a whole tin at one time and it was the funniest thing ive ever seen"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Derek: "no joke, i got my first rip from chase utley when i was 11..greatest thing that ever happened to me"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Joseph: "ant nothin better than sittin in the duggout with a fatty in hangin out with ur boys"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Nick: "skoal citrus makes the day better lol half the baseball team rocks a dip, of course we just cant get caught by the coach kind of a bummer"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Travis: "The bigger the dip, the better he plays!!"

Source: http://www.facebook.com/group.php?v=wall&ref=search&gid=2317662091

[Accessed 4/12/2010]

Miles: "ahh...i put half of my red man big in today during my game...i dedicated it to this great group"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2364882221 [Accessed 4/12/2010]

Sheldon: "chipper jones pokes his lips and gums with a pin before he lips in and he mashes, so him or swisher is the biggest dipper"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Dustin: "man theres nothin like a big pinch right before the game, during the game, and after on the way home haha....helps me drop bombs...it was mine and pres' JUICE haha" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2364882221 [Accessed 4/12/2010]

Kyle: "Chris Duncan=Best Dipper in Baseball"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Jordan: "how old was everyone when they first threw in a hammer? i was 13!" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Christian: "u gotta like the redman chew and dubble bubble mix that francona does too" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Rob: "dustin pedroia paks bigga bombs then ne one on the field" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Nick: "i have a poster of bonds with a lipper in his mouth and a tin in his back pocket hittin a ball now thats talent lol"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Mark: "the cool thing is that my coach doesnt even care...we pack the biggest bombs right in front of him and he doesnt say anything"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Nick: "watermelon?! damn that should be good...but does it keep the flavor and buzz goin? thats key"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Corey: "yo if u play baseball u gotta love paking dips i love kayak grape" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Ryan: "baseball and skoal make the best combo out there, a nice lip of spearmint while taking bp, theres nothing better"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Patrick: "hahah ya he does i was watcihng a sox game and after he hit a homrun he went to the dug out and packed him slef a nice lip of skoal"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Cameron: "Hurray Dip! I've got a fatty in right now before I go to class. Now only if I was watching a ballgame.

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Drew: "Troy Glaus hands down throws in the biggest daggers. And whenever its a rookie pitcher starting he throws in an extra big one for intimidation factors." Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Nick: "yo who saw the game 4 of the yank and indians....towards the end the camera guy had damon and jeter...and all u see is damon gettin rid of his bomb..lol"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541
[Accessed 4/12/2010]

Joe: "i saw a sox game a couple monthes back, beckett was pitchin and he was sittin in the dugout and all he was doin was takin a bomb out, and donnaly was also doin an interview with Nesn in the locker room in his locker was protein and a straight tin it was sick"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

RJ: "ill dip anything skoal..i just had the new skoal edge, gives a great buzz!!!" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Nick: "sitting in the bullpen the other day with a big league chew of grape bubbleicious and levi, it occurred to me that skoal should come out with grape dip.... yeah? no?" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Matthew: "nothing like a nice fat lip when your playing baseball"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541
[Accessed 4/12/2010]

Cory: "how is dustin pedroia in this group he packs an atomic bomb that could blow up all of japan every game"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Dustin: "who would ever thought johnny damon dips lol saw him spittin out a fatty over the rail in the dugout it was hilarious haha"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2364882221 [Accessed: 4/12/2010]

Joseph: "josh hamleton ive never seen him without one in ever"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Drew: "Common guys, have you ever seen a Brewers Game? Prince takes the cake on this award. At least a quarter of a tin everytime he is up to bat"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Dean: "Im gonna hav to second Josh Beckett. he always has a tin in his pocket a nice big lip in"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Jason: "chipper jones is the best dipper"

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Justin: "If you're not playing baseball, the best place to pack a fatty is definitely in the car."

Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Nick: "Baseball season is here baby, and skoal straight is still the only way to roll" Source: http://www.facebook.com/home.php?#!/group.php?v=wall&ref=search&gid=2365414541 [Accessed 4/12/2010]

Mr. PALLONE. Thank you, Dr. Connolly.

We are going to take questions from the members and I am going

to start with myself.

I am not trying to be difficult in any way, Mr. Prouty, but you took a lot of time to explain that the smokeless tobacco was essentially banned in minor leagues but you said in major league it is not and you cited the fact that basically it is legal and so why should we be pressured or whatever, I guess, to ban it. But it is obvious that you ban a lot of other things. I guess players aren't allowed to open a beer or mix themselves an alcoholic drink in the dugout, and also you banned the smoking of cigarettes, or Major League Baseball has banned the smoking of cigarettes in uniform in view of the public. I mean, cigarettes are legal, alcohol is legal. What is the difference? Why is it so important to continue the use of smokeless tobacco but not these other things? Why is it any different?

Mr. Prouty. Well, Congressman, first of all, let me say that there is a difference between cigarette smoking and smokeless to-bacco insofar as smoking affects the game. You can't smoke while you are playing. Cigarette smoking also has secondhand effects on other players. But I don't think we are here today to defend smokeless tobacco. What we are saying is that it is a legal product and it is legal in the United States for use. If you want to go about ban-

ning it, Congress should go about banning it.

Mr. PALLONE. No, I understand that, but I guess what I am saying is that is just seems strange to me. I guess when you negotiate a collective bargaining agreement, why is there not an effort to say pursuant to the collective bargaining agreement that smokeless to-bacco would be banned as well? I guess I am asking from the point of view of the players as well as from the point of view of the union. It doesn't make sense to me that you would have a lot of—that you wouldn't press to do the same thing. Is this coming from the players? Are they demanding that it not be prohibited? What

is the reason?

Mr. Prouty. Well, you know, in any organization, there are varying views. We have people who are all for using smokeless tobacco. We have people who are against it. We have a round of collective bargaining negotiations coming up. We can only look forward on this. We are just beginning to formulate our proposals on all kinds of issue. I am not the union. We represent the players. The players will get together and decide what issues to bring to bargaining. Mr. Manfred's side will get together and decide what issues they want to bring to bargaining. As he said, smokeless tobacco is a mandatory issue so if either side brings it up, we have got to talk about it. We hear what you are saying. We will take the concerns of everyone here back to the players. It is for the players to make a decision about what to go ahead and bring to the bargaining table, but rest assured, I will make sure based on the hearing today that they hear what you are saying.

Mr. PALLONE. I appreciate that. And then I wanted to ask Mr. Von Behrens, and again, I appreciate your being here today. When you said that you reached over 2 million kids in the course of your speeches and presentations, that is really amazing. But I wanted to go back. You mentioned when you first started using tobacco.

How much did your decision to start and use correlate with your passion for baseball, which actually you have, and do you think if you had known more about the health effects when you were a

young person you still would have used it?

Mr. Von Behrens. You know, I tell kids every day that if some-body like myself would have came and spoke to their school or my school whenever I was a young man, there is no way I would be sitting in front of you guys here today because I would have made an educated choice and I would have stopped using. This would have scared me enough into not using these products. You know, baseball had, like I said, marginal effects of why I used tobacco, guys. We are sitting here today and we are talking about baseball and spit tobacco, baseball and spit tobacco, and yes, I believe that they should not be able to use it on the field. It is like smoking a cigarette on the field. I am not going to get into that because that is not the type of person that I am.

But there are so many other things that we are overlooking. I am a competitive bass fisherman. I fish all over the Midwest. There are boats out there selling ads. They are boats advertising Longhorn tobacco. The guy who got second place in the Bassmasters last year fished out of a boat sponsored by Longhorn tobacco products. So there are so many other forms and there is a lot more of these types of people out there than there are potential baseball players. There is more hunters, there is more fisherman, there is more farmers, kids, people who aren't really that associated with baseball that are being affected by the advertisements and the ploy that

tobacco is a safer alternative to cigarettes.

Mr. PALLONE. But you are convinced that if we had more education and awareness, a lot of these young people would not start

using it?

Mr. Von Behrens. Definitely. You know, it irritates me when we talk about education because there is so many budgets cut that are in effect across the United States. There is people out there fighting to do their jobs to prevent you from using these products. They can't even do their job anymore because somebody wanted to build a road with the money donated to them from the master settlement agreement. So we need to first make sure that the master settlement agreement money goes into education. That is what it is meant to be used for, not to fix the roads, not to get somebody out of trouble, to educate youth. And if we educate youth, I think in the long term we will see our health and our financial well being get better. I spent almost \$3 million in medical expenses from what this product did to me, 3 million bucks to have surgeries, to have radiation treatment, to lay in the hospital for two months at a time, \$3 million. I don't know of one person who spent \$3 million or how much taxation you will make off of one person in their lifetime selling this product. It is a very harmful drug and we just need to put guidelines in and make it better and make kids understand what it can do to them.

Mr. PALLONE. Thank you.

Mr. Shimkus.

Mr. Shimkus. Thank you, Mr. Chairman.

Mr. Von Behrens, you have made Illinois proud.

Mr. Von Behrens. Thank you.

Mr. Shimkus. I appreciate you coming, and Mr. Garagiola, of

course, you made St. Louis proud.

Mr. Garagiola. Before you start, I have this DVD. It is the best piece of equipment I have to talk to people. It is all about Gruen and nobody else, and he talks to high school kids, and the Diamondbacks were good enough to make sure that it was distributed and the schools got it. Gruen was great, and I wish you could see the effect he had on the young people because when he walked out there, there was a collective "huh" and then he started, and boys, he knocked their socks off. I will never forget that, Gruen. Mr. Von Behrens. You know, I was—

Mr. PALLONE. Would the gentleman yield? And I am not going to take away your time. I will give you more time. What I was going to suggest, Mr. Garagiola, is that you have or can get us extra copies of that, we will circulate them to the members of the

Mr. GARAGIOLA. You tell me how many you want.

Mr. PALLONE. We will get back to you. And also I don't know if there is a transcript of it. We could enter that in the record. But we will look into that, all right?

Mr. GARAGIOLA. I will tell you what. I am going to give you that and the Bob Leslie tape when I ask Bob Leslie what is the toughest part of the day.

Mr. PALLONE. OK. Thanks.

Mr. Shimkus. And let me just follow up on that. You did talk about the No Chew Crew program with Arizona. Has that been accepted or replicated in any other ballpark organizations and stuff?

Mr. GARAGIOLA. I have been frustrated a lot. I am going to answer that question as honestly as I can. Only one other club called the Diamondbacks and said tell us more about it. That was the Marlins. And nobody else. This booklet, I want to give it to the little guys because I thought they could read it because it is a tobacco message but they could also color it, and Commissioner Selig, he gave me \$50,000 to make the distribution. One club, and I don't want to embarrass them, the girl says I am going to throw them away because we don't have any room to store them. I said no, you are not going to throw them away. I called the president of the club and we got them distributed. No, it was met with industrialstrength apathy.

Mr. Shimkus. Dr. Connolly, when you talk about the addictions, I believe there are social kind of addictions, peer pressure. Are you making a determination because social kind of addictions and peer

pressures or the physical addiction?

Mr. Connolly. Well, I think we have to understand that you have two different dosing mechanisms for nicotine. The cigarette, you get a rapid dose of nicotine and it falls off and sets a spike effect. It is very, very attractive because it is reinforcing and it has central nervous system effects. With smokeless, it is a slow effusion across the oral cavity, about 20 cell layers, and you get a general background dose. And then with a product like Copenhagen, you get a bolus of nicotine into the central nervous system. So it is a chemical addiction. The Surgeon General described it as such. And then we look at quitting patterns. We find it is about the same. It is equally hard for smokeless tobacco users and cigarette smokers to quit. They are about the same because they are dealing with a chemical addiction. Finally, what is disturbing is the increase in dual use that we are seeing in the American public, people using cigarettes and using smokeless, and what we may be observing is the emergence of dual dependency, someone being dependent upon cocaine and heroin at the same time. It is extremely hard because of the difference in dosing to treat dual dependency. This is a major concern that we have for the Nation is that young people seem to be using both now in particular parts of the country and it is going to be harder, I believe, to treat those dependencies.

Let me point out too, the players association has to step up to the plate here. I mean, we have to—

Mr. SHIMKUS. My time is—Mr. CONNOLLY. I am sorry.

Mr. Shimkus. I am going to address that, and we have been here a long time already, but I do think my colleague from Maryland, it does make sense if you have got an asset as the players' union does and as Major League Baseball does to protect the asset. I am a Republican. We believe in competitive markets. We want to protect collective bargaining and we want you all to work it out. I am not one to want government to intervene with a national law to say—because if we ban tobacco products, then we would have the underground economy, we would have the products just like we have illegal drugs, et cetera, et cetera. But it is always better, gang, if you do this and work this out, and I think you hear collective agreement by the panel that we would hope that in the next round you all would step up and lead by example and then you wouldn't be called back up here anymore for this issue.

Mr. Connolly.

Mr. Shimkus. Yes, sir.

Mr. Connolly. There is no silver bullet here. We need education for the kids, education for the players. We need treatment for those players. We need counseling. But we also need policies. You can't say one is going to work without the other. It is a combination of efforts.

Mr. Shimkus. Well, and Mr. Von Behrens mentioned the family, and leadership is not just professional sports. It is family. I caught in the hot summers of St. Louis and my parents gave me salt tablets because of sweating, and that was what was thought at the time.

We do appreciate your time and effort, and Mr. Chairman, I will yield back.

Mr. PALLONE. Thank you.

Chairman Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

As I understand the situation, if Major League Baseball wanted to ban the use of smokeless tobacco or cigarettes, they can just go ahead and do it when it comes to the minor leagues, but when it comes to the major leagues, they can't just go ahead and do it because you have to have a collective bargaining. The union represents the players in the major leagues but not in the minor leagues. Is that right, Mr. Prouty?

Mr. Prouty. Yes, that is correct.

Mr. WAXMAN. So the only way you would get to talk about the major leagues would be through collective bargaining agreement?

Mr. PROUTY. That is correct. It is a mandatory subject of bargaining.

Mr. WAXMAN. So you have to bargain this question out and have

it as part of your contract.

Mr. Prouty or Mr. Manfred, do either of you disagree with the harm that comes to the players after all the testimony you have heard today from the use of smokeless tobacco?

Mr. PROUTY. No, Congressman, we don't disagree at all. Mr. WAXMAN. And Mr. Manfred, you don't disagree, do you?

Mr. Manfred. No. As a matter of fact, we put extensive effort into trying to encourage our players at all levels, minor and major league, to not use smokeless tobacco.

Mr. WAXMAN. Do either of you disagree with the idea that children, young people are influenced by seeing behavior of players on

the field? Mr. Manfred?

Mr. Manfred. No, I don't.

Mr. Prouty. No, we don't disagree. Players are role models. We

don't dispute that.

Mr. WAXMAN. So then the question is, if there are health risks to the users and there is a problem in the message that is sent to the kids, you seem to both agree with that. Wouldn't you both be in favor of agreeing to not allow players to be using smokeless to-bacco on the field?

Mr. Prouty. Congressman Waxman, it is not as simple as Mr. Manfred and me just agreeing. We both represent constituencies. The union is a democratic organization. We have to go back to our members. We have to hear what—

Mr. WAXMAN. I understand that. What would be the argument against it?

Mr. Prouty. The argument against it is that it is a legal substance which can be used in this country.

Mr. Waxman. So are cigarettes. Mr. Prouty. So are cigarettes.

Mr. WAXMAN. Your members don't want to reopen that issue, do they?

Mr. Prouty. No, they don't.

Mr. WAXMAN. So you have two legal products. No one is disputing that. How about drinking beer or other alcoholic beverages? It is perfectly legal, may or may not be harmful, depending on the circumstance. Do any of your players think that they ought to be allowed to drink on the field?

Mr. Prouty. No, they don't. I don't believe so.

Mr. Waxman. So I am trying to understand an argument they might make on smokeless tobacco. If it hurts the health of the players and it influences adversely kids to use a product that is going to harm their health, I would hope you would take back to your members that they shouldn't stand in the way of what Major League Baseball did when it came to the minor leagues and put in the same policy for the major leagues.

Mr. PROUTY. Absolutely, Congressman. You can be assured we will take back the concerns that we have heard here today and the players will continue that along with all the other issues and we

will bring it up in the next round of bargaining if that is what they decide to do. It is a democratic organization. I can't promise you here today it will be brought up. I can promise you that I will bring back and make them understand as we did with steroids and other issues you are aware of exactly what Congress feels about this.

Mr. WAXMAN. What if your players said to you I don't want to have a ban on steroid use because we think it helps us improve our performance? Would the players advance the argument in the collective bargaining agreement that there shouldn't be any ban on

performance-enhancing drugs?

Mr. Prouty. Congressman, that is not where we are. As you know, we went through a series of-

Mr. Waxman. I remember. I remember it well. I am just obvi-

ously pointing out the illogic.

Mr. Prouty. But, no, I understand that. But if you remember, the process that we went through every time was, we went back and held meetings with players and developed a consensus about this is what has got to happen, these are the risks, this is the testing program and frankly, if we don't act, Congress is going to act but we would rather settle it by collective bargaining. In the end, that is what we did was settle it by collective bargaining, and you endorsed what came out of that.

Mr. WAXMAN. Let me ask you if you will be willing to start this process of consultation with your members now so you can be ready with a consensus position to allow this to be part of the collective bargaining when your contract is next up.

Mr. Prouty. Yes, we will, as I said before, bring this back to the

membership and start consulting.

Mr. WAXMAN. Good.

Thank you very much, Mr. Chairman. I appreciate everybody's testimony today.

Mr. PALLONE. Thank you, Chairman Waxman.

The gentleman from Indiana, Mr. Buyer.

Mr. BUYER. Thank you very much.

I want to agree with the comment, educate, educate, educate. I think you are right. And in a free society, I believe there are always going to be differences of opinions based on differing values, beliefs, perceptions and also due to the imperfections of reason. So in the effort to educate, educate, educate, we also have to nourish the hope that how do we achieve improvements to public health. Now, when you make that effort, you cannot ignore science. Now, what was challenging from the first panel was to have an individual who would not acknowledge that there is a continuum of risk among tobacco products. Now, I don't smoke. I don't advocate for people to smoke. I also recognize that it is a lawful adult product and that it is a product that we don't want in the hands of children. So I also acknowledge as a worthy effort to prevent role models from using such a product and what can we do to make sure that children don't gain access.

Well, you know, we have done a lot of things. Not only have we made it illegal for individuals under the age of 18 to gain access to these products, but you know what? The master settlement agreement. I am surprised by the advocates of this panel that you haven't talked about the master settlement agreement and the fact

that the States out there are not utilizing monies collected not only from the MSA but also from cigarette taxes to be spent on education programs. So in fiscal year 2010 alone, and this is according to the document that I have now submitted to the record titled A Broken Promise to Our Children. It states that in the current fiscal year 2010, States will collect \$25.1 billion from the tobacco settlement and tobacco taxes and they will spent just 2.3 percent of it, which is approximately \$560 million, on tobacco prevention and cessation programs. Now, when we passed Mr. Waxman's bill, I had offered an amendment. I had offered an amendment for us as a Nation to improve public health to acknowledge the continuum of risk and is it possible to migrate people from smoking to smokeless to finally quitting. Is that possible? When in fact there is a crucible out there for which we can look at, which is called the Swedish experiment. Incorporated in that amendment was also the advocacy on behalf of Ms. Blackburn to actually state that, you know, States, you should be required to spend a portion on education, a portion of the MSA. That was defeated. That effort was defeated here on the committee and it should not have been. Because those of whom will acknowledge and actually say that smoking a cigarette is just as bad as utilizing a smokeless tobacco product ignores science. Because there is truly a difference in the continuum of risk.

Now, I don't advocate the use of either of those products but to say that a snus product that eliminates 99 percent of the nitrosamines and you have got a 1 percent of health risk versus the 100 percent from a cigar ignores science. And so it is challenging for me because I look at this and say I agree with the testimony of educate, educate but why would the advocates of abstinence then not be willing to educate tobacco users that there truly is an opportunity to lessen the risk, that if you can reduce the thousands of constituents and toxins from smoking to move to smokeless, that that in fact can make your healthier. But the complete goal here is actual cessation of the tobacco product. To ignore that is also then to ignore science and ignore the advocacy to educate, educate, educate. A nation cannot be ignorant sustain freedom. So as a government when you ask government for its help and assistance, we as a government need to be honest with regard to is our advocacy with regard to availability of tobacco products. Now, for those of whom are advocating abstinence, if you want to advocate the complete outlawing of tobacco products, go ahead and say that if that is what the advocacy is. But that is not what this committee has chosen to do. It is not as a country what we have chosen to do.

So I just—I want to thank all of you for your efforts. It is unfortunate with regard to Major League Baseball and the players' union that my sensing is that you have been brought here to testify and the committee is somehow strong-arming you with regard to what should occur or not occur within collective bargaining. I think that is wrong if we are going to actually say that the marketplace is a sacred place. And so that is unfortunate. You can choose to do what you believe is morally right, and I believe that you have that sense and that can happen at the table, but for us to strong-arm you and to dictate as to what you should and shouldn't do and sup-

plant our moral understanding upon you, wow, if that is what we want to do, then we should have made tobacco products illegal instead of passing that bill.

With that, I yield back.

Mr. CONNOLLY. Could I just comment?

Mr. PALLONE. I think we should probably let them respond if they want.

Mr. Buyer. I did not ask a question. I yielded back. I made a statement.

Mr. CONNOLLY. As a person—

Mr. PALLONE. He has yielded back, Dr. Connolly.

Ms. Blackburn.

Mrs. Blackburn. Thank you, Mr. Chairman, and mine is more of a statement than a question. I do appreciate that all of you are here, and Mr. Buyer mentioned some of the frustration that we have with this issue. As I said in my opening statement and in my questions, in the 110th Congress, in the 111th Congress, there was an opportunity to expand SINAR and to take care, special care, extra care to address this issue of teens and smoking.

Now, I was interested in the testimony of a couple of you, Mr. Manfred, in your testimony, and Mr. Garagiola, in yours. You talk about education and the importance of education, and why this needs to be expanded, and I liked the example of the No Chew

Crew.

Mr. GARAGIOLA. But you need money.

Mrs. Blackburn. OK. Then is this a program that would function well with some of the master settlement dollars? Have you looked at that? Are you seeking to move forward with expanding that program through the—the money is there. I mean, that is—

Mr. GARAGIOLA. The money is there but I think it is—I have a clipping that I have saved. This is from 2001. In North Dakota, legislators have been criticized for considering using a portion of the settlement money to built a state morgue. In Alabama, legislators allocated a portion of the settlement to fight gangs and satanic worship in public schools. In Montana, officials funded a juvenile delinquent boot camp. Tobacco-growing States like North Carolina, South Carolina, Virginia, funds have been set aside to compensate tobacco farmers for losing crop revenues as smoking declines. The problem comes when you call these people. Mike Moore, the attorney general from Mississippi, we thought we had the money, and when you call the line is busy, they will get back to you. I am still waiting for calls from some of these guys.

Mrs. Blackburn. Well, and the legislation I have brought before this body that action was not taken on would have addressed the usage of some of these master settlement funds and would have required the States to meet certain expanded criteria. There is a way

to address this.

Mr. Manfred, I think you had a couple of thoughts, and I do appreciate your testimony, and when you talked about the minor league policy that is there on smoking and tobacco products and the compliance rates on that, and I wanted to know if the smoking cessation counseling programs that are provided by the clubs' employee assistance personnel, to what extent that has been success-

ful and if you all are doing outreach specifically geared toward children.

Mr. Manfred. Let me start with the employee assistance programs. I think when you talk to our employee assistance professionals as a group, the 30 of them, we get them together twice a year, and I think that in all candor, they feel that they have very good programs. They feel that they have a moderate degree of success, and the single biggest frustration that you hear from them is, people go through the programs, they do well, they stop and then they return to use. You know, if I had to summarize what our very long discussions with this group, that is how I would summarize it.

In terms of outreach, Major League Baseball has been committed to the NSTEP undertaking for years and years. I think Mr. Garagiola referred to the fact that Commissioner Selig allocated \$50,000 recently for a specifically child-directed program. He is holding up the pamphlets from that program. Commissioner Selig himself sees this as a public health issue, and I think that it is fair to say that our efforts in this regard both internally and externally will continue.

Mrs. Blackburn. I appreciate that.

I will just close by saying from our perspective, there has been an opportunity to address this. We have legislation. The SINAR language has worked. We don't need to reinvent the wheel. The goal is to make certain that children are educated and realize the dangers of tobacco use. As a mom, as a former Lung Associate volunteer, as the former president of that board, the education programs have been vitally important and that is how we are going to change this, and there does exist an avenue for that and I think it is regretful that this committee did not take up the opportunity to address that and I would have preferred out time today be spent on some other components that addressing some things in the health care bill that need to be done or addressing getting a federal budget together which I am understanding the Democrat leadership in this body does not want to do.

With that, I yield back. Mr. PALLONE. Thank you.

There are only a few of us left so we are just going to have a second round for whoever wants to ask questions, and I am going

to yield myself some time.

I asked Mr. Prouty before about a commitment to bring this up, and I think Mr. Waxman did also, to bring up the issue of smokeless tobacco in the context of collective bargaining agreement, and I just wanted to ask Mr. Manfred the same thing, if you would be willing to say that you would make the issue of smokeless tobacco a priority when you negotiate with the players over collective bargaining? Would you and the commissioner fight to try to end the use of smokeless tobacco by major league players? I mean, I know that you don't have—you know, a lot of this depends on what happens but we are still trying to at least get you and Major League Baseball to say look, we will try to make this a priority, we will bring it up, we are committed to putting an end to it in the same way you have with the minor leagues.

Mr. Manfred. We have begun our preparations for 2011 already. I think that Commissioner Selig's directive that Dr. Shaha make a presentation to the safety and health committee is indicative of his commitment to the idea that this issue needs to be addressed in 2011. I can also tell you that in our conversations with individual teams, we have had a number of teams raise this issue as something that we need to be putting on the table in 2011.

Mr. PALLONE. But can you just go beyond that and say that it

is a priority for that purpose?

Mr. MANFRED. I can say—certainly I can say this, that for Commissioner Selig it is a priority in terms of the issues that we have discussed so far. I think that is an accurate statement.

Mr. PALLONE. I appreciate that.

I am going to yield back and ask Mr. Shimkus if he would like

to say anything or ask any more questions.

Mr. Shimkus. No, I just appreciate the panelists. I think my colleague, Congresswoman Blackburn, makes a good point, and I would request that maybe the full committee chairman bring in the States and ask them to use their master settlement money on the tobacco to print your brochures, to print the DVDs and get them in all the schools across the country. That might be a good use of that instead of some of the other things that Mr. Garagiola highlighted in that old article. I mean, if we are serious about educating, we ought to be about the business of educating, and I appreciate those who are doing their part with their own ability, but again, I think government has dropped the ball on some of these aspects, and I yield back my time.

Mr. PALLONE. Mr. Buyer, no additional questions? OK.

Let me thank all of you, really. I thought that his was very worthwhile today. It is obviously an issue that Mr. Waxman in particular but many members of the committee have cared about for a long time, and I also appreciate the fact that some of you are willing to take it back with the major leagues and try to address it. I think it is very important to us, so thank you very much.

The way we operate is that you may get additional written questions within the next 10 days or so that we would also ask you to

respond to as quickly as possible.

Thank you. And with that, the subcommittee hearing is adjourned.

[Whereupon, at 1:28 p.m., the Subcommittee was adjourned.] [Material submitted for inclusion in the record follows:]



The Good News and the Bad News about Smokeless Tobacco and Sports

Written Statement of Dr. Cheryl Healton, Dr. P.H., CEO and President of Legacy
Submitted to the Health Subcommittee of the Committee on Energy and Commerce
of the House of Representatives

April 14, 2010

Mr. Chairman and other members of the subcommittee, I appreciate the opportunity to submit this testimony today and would especially like to thank Mrs. Capps for alerting me to the topic of today's hearing, the impact of smokeless tobacco on our nation's youth and its use in Major League Baseball.

Like many issues in health, there is good news and bad news surrounding smokeless tobacco use. First, let me address the had news:

Smokeless tobacco use is on the rise among teenage boys. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) most recent National Survey on Drug Use and Health, while overall usage levels of smokeless tobacco were stable between 2002 and 2007, certain subpopulations experienced increases. Chief among those were increases among boys aged 12-17, moving from 3.4% in 2002 to 4.4% in 2007.¹ This increase highlights the need for strong messages to counter act the industry's advertising, and for strong role models – including professional baseball players – to prevent youth from starting to use these highly addictive products in the first place. It is important not to forget that nicotine is still the main ingredient in smokeless tobacco and it is one of the most addictive agents on earth.

Tobacco Companies have increased their marketing and advertising spending. According to the most recent Federal Trade Commission Smokeless Tobacco Report, advertising and promotional expenditures for smokeless tobacco increased from nearly \$251 million in 2005 to just over \$354 million in 2006.

- o Direct mail spending and point-of-sale advertising increased slightly from 2005 to 2006; ii
- Spending on promotional price discounts jumped from \$99.7 million in 2005 to \$203.7 million in 2006;¹¹
- Expenditures in connection with sports and sporting events rose from \$15.7 million in 2005 to \$16.9m in 2006.

Tobacco control programs cannot begin to compete with the level of funding promoting the use of smokeless products. Tobacco control programs are truly David to the industry's Goliath, and have an uphill battle to counteract industry messages. In particular, baseball players and other sports role models should not give the tobacco industry free advertising during games by being shown on television using tobacco products. It is critical to promote messages that resonate with young people about the dangers of smokeless tobacco and to ensure that everyone knows that there is no such thing as a safe tobacco product.

There is evidence that a new generation of smokeless users is emerging. An important study of tobacco industry documents has shown that in recent years there has been a subtle shift in both the marketing and use of smokeless tobacco users from a rural, older-user focus, to a younger, urban, user. Additionally, the tobacco industry markets smokeless products as a solution to smoking bans by providing tobacco users with a way to get their nicotine fix when they can't smoke. ^{III} This has had a particular resonance with youth. This is startling when you learn that in 2007, 52.8% of past month smokeless users ages 12-17 also smoked cigarettes in the past month. ^I Many tobacco control experts



about this "dual use" of smokeless tobacco and cigarettes which maintains nicotine addiction while reducing important incentives to quit using tobacco.

Despite these disturbing trends, there is some good news, particularly in regard to the sports and smokeless tobacco

Smokeless tobacco use among baseball players may be becoming less prevalent There are at least two studies that confirm a reduction in smokeless use by several professional baseball organizations^{iv,v} In 1993 Major League Baseball instituted a ban on tobacco products in the minor leagues. However, there are no such bans in the major leagues. More needs to be done and I encourage MLB to issue a similar ban on tobacco products in the major leagues.

New legislation restricts tobacco sponsorships of sporting events. The new law granting FDA the authority to regulate tobacco also contains restrictions on sponsoring sporting and other cultural events in the United States. This will mean that smokeless tobacco companies will no longer be able to sponsor rodeos, baseball games, or automobile races. Indeed just this week, it was announced that the largest rodeo in Wyoming will, for the first time in decades, not be sponsored by US Smokeless Tobacco. The state health department will be sponsoring the event instead, with a message promoting the state's quit tobacco program. This is a victory for the health of the people of Wyoming as well as for the young athletes participating in the rodeo.

While these are encouraging developments, there is still much more work to be done. I look forward to working with all interested parties to ensure that effective programs are available to encourage youth not to start using all tobacco products, very much including smokeless products, in the first place, and to help those who do use it to quit. Hearings like this that highlight the tobacco problem and the importance of role models such as baseball players and other athletes in influencing our youth to make healthy choices are a step in the right direction. Thank you again for holding this hearing on such a timely and important topic.

¹ Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (February 19, 2009). *The NSDUH Report: Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007.* Rockville, MD. ³¹ Federal Trade Commission (August 2009). *The Smokeless Tobacco Report for the Year 2006.* Washington, DC. ³¹

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Written Testimony from the American Association for Cancer Research on "Smokeless Tobacco: Impact on the Health of our Nation's Youth and Use in Major League Baseball"

April 14, 2010

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On behalf of the American Association for Cancer Research (AACR), the world's oldest and largest professional organization dedicated to advancing cancer research, thank you Chairman Pallone and Members of the Committee on Energy and Commerce Subcommittee on Health for holding this important hearing to bring attention to the serious problem of smokeless tobacco.

Smokeless tobacco use causes cancer and other serious health problems, leading to death or substantial reduction in quality of life. Despite decades of solid scientific evidence to the contrary, the gross misperception that smokeless tobacco is harmless still thrives, and new users are becoming hooked daily.

Currently, tobacco kills more than 440,000 people in the United States and more than five million worldwide every year. Tobacco use is on the rise globally, and the death toll is expected to top eight million a year by 2030 if current trends continue. We must do everything in our power to stem the global tide of tobacco-related death and suffering and improve public health. A special emphasis on eliminating tobacco use by children and young adults is imperative, and efforts to call attention to the harms of tobacco, such as this Subcommittee's hearing today, are commendable.

The AACR is proud to offer the expertise of its membership of over 31,000 cancer researchers, physicianscientists, other health care professionals, and survivors and patient advocates to this Subcommittee in its efforts to protect young people from the dangers of smokeless tobacco products, and more broadly, to curb the deadly tobacco epidemic.

Smokeless Tobacco Use Causes Cancer

In the United States alone, cancer kills more than a half a million people every year. Sadly, nearly a third of those deaths are attributable to tobacco use, a completely avoidable loss of life.

Smokeless tobacco, in particular, contains at least 28 cancer-causing agents¹ and its use increases the risk of developing cancers of the oral cavity (which includes the lip, tongue, cheeks, gums, and the floor and roof of the mouth), esophagus and pancreas.² Leukoplakia, white patches and oral lesions on the cheeks, gums, or tongue that can become cancer, receding gums and gum disease, and decay of tooth structure are also possible consequences of smokeless tobacco.

Nearly a quarter century ago, the U.S. Surgeon General declared that use of smokeless tobacco "is not a safe substitute for smoking cigarettes." For decades, the National Cancer Institute has also warned the public to avoid and discontinue the use of all tobacco products, including smokeless tobacco. Yet the common myth that smokeless tobacco is a safe alternative to smoking persists, and the dangers of smokeless tobacco remain largely unknown or dismissed. All the while, smokeless tobacco has continued to wreak harm and addict new generations of tobacco users.

In 2007, an estimated 8.7 million Americans, aged 12 or older, were current users of smokeless tobacco. This number is evidence that a renewed and more concerted effort is needed to identify effective approaches to reaching the public with the message that all forms of tobacco can be lethal. The AACR believes that we must develop evidence-based strategies for more effective public communication to prevent, reduce and eliminate tobacco use and to guide public health policies and clinical practice.

Smokeless Tobacco Use Serves as a Gateway to Lifelong Addiction and Dependence While the prevalence of smokeless tobacco use remains lower than cigarette smoking, there are several reasons it earns special attention, including a recent increase in prevalence among youth, suggesting it is a growing problem, as well as the fact that use of smokeless tobacco can be a gateway to cigarette smoking.

According to the recent "Monitoring the Future Study," prevalence of smokeless tobacco use increased over the past three to four years in 10th and 12th grades to thirty-day prevalence of 6.5 percent and 8.4 percent among 10th and 12th graders, respectively, in 2009. ⁶ Concomitant with increased prevalence was a decrease in perceived risk of regular use.

Once experimentation with smokeless tobacco begins, addiction and dependence soon take hold. Smokeless tobacco, similar to virtually all tobacco products, contains the highly addictive drug nicotine. According to the National Institutes of Health, the amount of nicotine absorbed from smokeless tobacco is three to four times the amount delivered by smoking a cigarette. Research suggests that more nicotine is absorbed from smokeless tobacco than from cigarettes and that the nicotine stays in the

¹ National Cancer Institute. Monograph 2: Smokeless Tobacco or Health: An International Perspective. 1992

² Secretan B, Straif K, Baan R, et al. A review of human carcinogens--Part E: tobacco, areca nut, alcohol, coal smoke, and salted fish. Lancet Oncol 2009; 10: 1033-4

³The U.S. Surgeon General. The Health Consequences of Using Smokeless Tobacco. 1986 ⁴ www.cancer.gov/cancertopics/factsheet/Tobacco/smokeless

⁵ Substance Abuse and Mental Health Services Administration. Results from the 2008 National Survey on Drug Use and Health: National Findings, Rockville, MD; 2009

 $^{^{6}\} www.monitoring the future.org/press releases/09 cigpr.pdf$

bloodstream for a longer time. Upon quit attempts, smokeless tobacco users exhibit nicotine withdrawal symptoms similar to cigarette smokers.

Studies indicate that smokeless tobacco users are more likely than nonusers to become cigarette smokers. High school students who are frequent users of smokeless tobacco are also more likely to try illicit drugs including marijuana, cocaine or inhalants. Because smokeless tobacco can serve as a gateway to smoking, it is critically important to include strategies related to smokeless tobacco use in comprehensive prevention and cessation programs.

Prevention of tobacco initiation is central to avoiding lifelong addiction and increased risk of disease. The AACR believes that we must develop new evidence-based strategies to more effectively prevent the initiation of tobacco use, especially for youth and young adults.

Implementation of the Family Smoking Prevention and Tobacco Control Act
The AACR applauds the Congress for approving the Family Smoking Prevention and Tobacco Control Act
of 2009 (FSPTCA), which grants the U.S. Food and Drug Administration (FDA) authority to regulate
tobacco products. The law presents the United States with an historic opportunity to dramatically
reduce tobacco use—including smokeless tobacco use.

Restrictions on marketing and sales to youth are already being implemented and requirements for larger, stronger warning labels on all smokeless tobacco packages and in advertisements will take effect this summer. Notably, the FDA was also given authority to further restrict or prohibit tobacco product advertising and marketing, as necessary, to promote public health.

The law prohibits the use of the descriptors "light," "low," and "mild" because they are deceiving to the consumer. Claims of reduced health risks for new smokeless and other tobacco products will now have to be substantiated by scientific evidence and evaluated by the FDA before such claims can be made.

Importantly, the FDA was granted authority to require changes to tobacco products that the agency finds to be appropriate for the protection of public health. Extensive disclosure by the tobacco industry, including product ingredients and any studies on the effects of the ingredients, such as toxicology, is required and will help the FDA determine what components contribute to tobacco harm and addiction. Through its new product standard authority, the FDA may require the elimination or reduction of certain ingredients or byproducts of tobacco products to promote public health. This could have a tremendous impact on public health if, for example, the FDA required the reduction of the addictive agents in tobacco to levels that are not addictive to anyone, which would both stop the progression from experimentation to addiction and foster complete cessation.

FDA authority over tobacco products is a huge step forward in tobacco control; however, the FDA will need support from the scientific community as it develops a comprehensive framework for the

www.cancer.gov/cancertopics/factsheet/Tobacco/smokeless

⁸ Centers for Disease Control and Prevention. Preventing tobacco use among young people: a report of the Surgeon General. 1994

evaluation of tobacco products and manufacturer claims. The AACR believes the framework should include all relevant validated approaches for evaluation, including laboratory studies, clinical trials, and epidemiological studies, and surveillance. The evaluation of manufacturer claims will need to be assessed through human studies of sufficient size, scope and duration. This framework should provide a means to evaluate the impact on both toxicity and consumer perception and use in order to assess individual and population health effects.

AACR's Call to Action

While tobacco use has declined dramatically in the last half century, an estimated 70.9 million Americans still currently consume tobacco in some form. More disheartening is that, globally, tobacco use is on the rise, with a current estimate of 1.3 billion smokers. Given that tobacco accounted for approximately 169,000 cancer deaths—nearly a third of all cancer deaths—in 2009 in the United States alone, the AACR is intensely interested in working to combat the tobacco epidemic.

Last fall, the AACR convened the AACR Task Force on Tobacco and Cancer, a twelve member body of experts from disciplines across the spectrum of tobacco-related research, to identify and pursue tobacco-related policies and scientific priorities for the AACR. The task force developed a comprehensive policy statement on tobacco, ¹⁰ published yesterday in *Cancer Research*, a journal of the AACR, as a call to action to the broad research community and all who are concerned about public health to work together toward eliminating the burden of tobacco use and attendant disease.

The AACR believes there is a clear imperative to eliminate the burden of tobacco use and attendant disease by advancing science and communicating scientific breakthroughs to the public, funders and regulators. Efforts to reduce tobacco use must go hand in hand with efforts to reduce the disease and suffering caused by tobacco. The AACR urges the adoption of a robust research agenda that supports the development of the most effective policies for tobacco and cancer control and promotes advances in approaches to addiction and tobacco-related disease. The AACR calls on its members and the research community at large to address the tobacco problem through transdisciplinary approaches, looking across the entire tobacco use and harm continuum, from preventing initiation and facilitating cessation to elucidating biological mechanisms to improve prevention, early detection, diagnosis, and the treatment of diseases caused by tobacco use.

The AACR recognizes that while smoking is currently the largest problem, other forms of tobacco consumption, including use of smokeless tobacco products or smoking of cigars, pipes, and waterpipes, warrant increased attention and vigilant surveillance. Enhanced and better coordinated surveillance efforts are necessary to monitor all tobacco products, tobacco use, and tobacco-related disease, both in the United States and globally. Such surveillance is essential to understand the full scope of the problem—who is using which tobacco products, why they use them, and what problems result from their use—and the resulting knowledge will facilitate the development of effective approaches to countering tobacco.

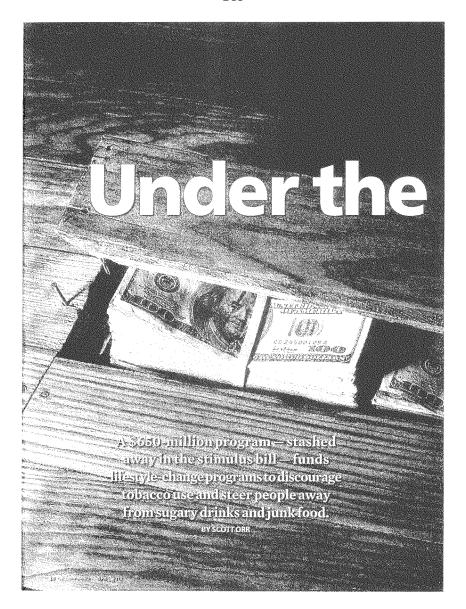
¹⁰ Available at: cancerres.aacrjournals.org/cgi/rapidpdf/0008-5472.CAN-10-1087v1.pdf

Much needed progress in the prevention, diagnosis and treatment of tobacco-related cancer will come from supporting research that addresses the following: the potential harms of current and new tobacco products; the impact of altering the levels of addictive components in tobacco products; the identification of risk and risk-reduction measures for current and former tobacco users; enhanced early detection methods for tobacco-related cancers; and effective treatments against tobacco-related cancers tailored to the unique effects of tobacco on cancer.

The AACR strongly advocates for an increased investment in tobacco-related research, commensurate with the enormous toll that tobacco takes on human health, to provide the scientific evidence to drive the development of effective policies and treatments necessary to dramatically reduce tobacco use and attendant disease. With particular regard to the important subject of today's hearing—the impact of smokeless tobacco, the AACR urges an increased investment in research to identify effective approaches for reducing smokeless tobacco initiation and use, and to pioneer new methods for reducing the toxic and adverse health effects of smokeless tobacco.

The AACR has been moving cancer research forward since its founding in 1907. The AACR and its more than 31,000 members worldwide strive tirelessly to carry out its important mission to prevent and cure cancer through research, education, and communication. Celebrating its 101st Annual Meeting this coming weekend in Washington, DC, an estimated 17,000 attendees will share in exciting advances across the spectrum of cancer research. The AACR has dedicated a special policy session to the global tobacco epidemic to bring attention to the issue and cultivate interest among cancer researchers.

The AACR urges all stakeholders worldwide to work together to develop and implement effective tobacco control and cancer control strategies. The AACR stands ready to help Congress and the Administration in their efforts to reduce tobacco use in all populations.



Floorboards

When the \$787 billion stimulus package passed in early 2009, it was held up as a solution to America's mounting economic woes, one that would buoy the economy, create jobs and steer America clear of economic Armageddon.

At the time, little was said publicly about other goals tucked away deep within the bill's 1,072 pages. Now, more than a year after the bill was enacted, some of its lesser known provisions are coming to light, including a \$650 million grant program designed to encourage state and local governments to try and force lifestyle changes on their citizens.

The program devotes almost half-abillion dollars to grants for state and local programs to discourage the use of tobacco and to steer people away from sugary soft drinks and junk food. And the grants come with strings—states only receive the money if they promise to take action in each of the "MAPPS" categories: media, access, pricing, point of purchase and social support/services

support/services.

Of course, cash-strapped states jumped at the opportunity to enrich their treasuries by submitting grant applications for programs and projects gram envisions a raft of new state and >>>

that could have sweeping effects on the convenience retailing industry.

Money for Nothing

The program envisions new state initiatives to restrict how and where to-bacco is sold and how to display and advertise tobacco, food and other items. It also will fund initiatives to require new signage at retail, including posting the nutritional content of food and alerting consumers to the levels of fat, sait and other substances in the products they buy. In short, the products they buy. In short, the products

"It's very difficult to see how encouraging people to quit smoking, or to eat better, does anything to stimulate the economy

or create jobs."

Lyle Beckwith, NACS senior vice president of government relations

local regulations to force convenience stores, restaurants and other businesses to take steps to guide consumer choice.

To be sure, discouraging smoking and fighting obesity are laudable goals, but should they really be part of a bill designed to create jobs and stimulate the economy?

"It's very difficult to see how encouraging people to quit smoking, or to eat better, does anything to stimulate the economy or create jobs. It's like they're saying, 'Okay, Joe Six Pack, you're out of work, you can't support your family, but at least we can help you quit smoking and stop drinking soda," said Lyle Beckwith, NACS senior vice president of government relations.

With less than one-third of the grant money awarded, state and local governments are already preparing to implement their plans. And Beckwith said convenience store operators should mobilize to educate policy makers about

the effects these programs could have on local economies and convenience stores.

Specifically, the stimulus package, called the American Recovery and Reinvestment Act of 2009, contained \$650 million for the U.S. Department of Health and Human Services and the Centers for Disease Control and Prevention(CDC) to set up a program called Communities Putting Prevention to Work (CPPW). The program calls for grants totaling \$493 million through the "States and Territories Policy and Environmental Change" and "Community" initiatives.

Who Gets What?

In February, the government issued the first \$120 million in awards for states and territories. All 58 applications — from all 50 states, Washington, D.C., Puerto Rico, American Samoa, Federated States of Micronesia, Guam, Marshall

A Few State "Winners"

Some of the state programs selected for additional grant awards include: Colorado: \$1.2 million to advance a comprehensive statewide youth tobacco access policy; increase statewide awareness of the health implications of excess salt; reduce consumption of sugar-sweetened beverages; and develop and implement model food policies for schools statewide

Massachusetts: \$1.2 million to Increase restrictions on retail and outdoor advertising, ban outdoor advertising of cigars within 1,000 feet of schools, parks and playgrounds; include all tobacco products in other advertising restrictions; and require a health message for every tobacco advertisement in any retail store

New York: \$3 million to promote the effective implementation of statewide menu-labeling requirements, including calorie postings, for menus and menu boards of chain restaurants; promote the implementation of a ban on the sale of items containing trans fat; and reduce consumption of sugar-sweetened beverages

Delaware: \$1 million to promote plans to force an increase in the price of tobacco products other than cigarettes, such as cigars and smokeless tobacco

Texas: \$2.8 million to promote and support breast-feeding statewide

Islands, Northern Mariana and Palau—received funding for "nutrition, physical activity and tobacco control." Each state got at least \$335,801 and the territories got a minimum of \$99,980 in "base" funding.

In addition to the "base" grants, part of the \$120 million was doled out as competitive grants, with states submitting widely varying plans in the competition for funding.

Applicants for a slice of the stimulus pie were encouraged to develop a program not only to increase access to healthy food and drinks, but also to try and reduce the availability of less healthy products. States wishing to get in on the cash flow were also asked to try and influence pricing to discourage people from buying tobacco products and to work toward tobacco usage bans through zoning restrictions.

The application also calls for "sales restrictions" that ban certain retailers from selling cigarettes altogether and pricing regulations aimed at discouraging purchases. Bans on free samples and price discounts were suggested as well.

The program aspires to tell retailers how to price tobacco products, and it also suggests restrictions on how they can display tobacco. Restrictions on instore promotion and advertising could include banning behind-the-counter stacked cigarette shelving, which is specifically cited in the grant announcement as tobacco "power walls."

The government's grant announcement contained a wide range of suggested programs that state and local governments could implement at the tax payer's expense. The announcement was remarkable in its specificity, pointing out, for example, that:

"Healthier foods are generally more expensive than less healthy foods, posing an economic barrier to healthier eating, particularly among lowincome populations. Pricing strategies can be used to promote healthier foods and beverages through decreasing their relative cost."

- "Less healthy foods and sugar-sweetened beverages (SSBs) are readily accessible in homes, schools, work sites and communities. Limiting availability and accessibility of SSBs can decrease SSB consumption and increase the consumption of more healthful beverages."
- "Signage for healthier vs. less healthy items can be implemented in a number of settings, including restaurant programs, stores where food is purchased and in the workplace."

While convenience stores are not specifically mentioned in the announcement or in the grant summaries, they would clearly be targets of many of the restrictions — and with the help of federal funds. The announcement contains no definition of restaurants, for example, so rules created by states presumably would apply to any establishment that serves food.

Many of the states made clear they would be seeking new regulations on products that are the mainstays of convenience store sales.

Hidden Agenda

According to NACS State of the Industry data, more than 60 percent of all cigarettes are purchased in convenience stores and tobacco products make up, on average, 34 percent of in-store sales. Pre-packaged beverages make up more than 11 percent of the industry's in-store sales, which is more than beer, wine and liquor combined.

Oddly, the millions of dollars reserved for federally funded lifestyle guidance



While convenience stores are not specifically mentioned in the announcement, they would clearly be targets of many of the restrictions—and with the help of federal funds.

was stashed away in the deep recesses of the mammoth piece of legislation — even after a public furor forced Senate Democrats to remove \$75 million in funds designated to help people quit smoking.

Republicans and other opponents of the bill cited that funding as an example of wasteful spending aimed at certain lawmakers' pet issues rather than at the overarching goal of boosting the economy. Democrats agreed to abandon the original anti-smoking language, along with \$400 million to fight sexually transmitted diseases and HIV, after it became clear the public was not interested in funding programs outside the bill's stated intent.

Challenged by CNN on the wisdom of putting millions for anti-smoking programs into a bill intended as an economic stimulus, the language's lead sponsor, Senator Tom Harkin (D-IA) could not even predict how many Americans might end up quitting as a result of the spending.

"Well, I don't know, the money goes to the secretary of Health and Human Services and that will go out to various programs that are effective, that are proven effective in the past. I can't give you a number right now but for every, for every, I don't know the exact number, but for every 10 dollars or so we spend on smoking cessation programs, we can see the effect of people getting off of smoking." Harkin said.

Kate Cyrul, Harkin's spokeswoman, told ABC News that the senator "believes we must reduce health-care costs, but the arguments over the smoking-cessation funding created a distraction. We are committed to getting this to the president's desk. In that spirit, the smoking cessation funding came out of the bill."

The Center for Consumer Freedom, a non-profit group that advocates for personal responsibility and consumer So what we have here is a \$650-million program stashed away in a major piece of legislation that funds lifestyle-change programs, despite sustained objections to antitobacco language.

choice, says the grants are yet another government effort to prevent people from making up their own minds about the products they consume: "These 'recovery' grants may simply be a new food-police approach to the familiar goals," the group said. "It's hard to see how job loss fits into the feds' plan for economic stimulus. Maybe the grants are just a way to help diet dictators 'recover' from binging on heavy-handed nay-saying and stay gainfully employed."

A Contradiction in Terms

A close examination of the more-than-100-page grant announcement and the project summaries submitted by state and local governments points to a clear contradiction on whether or not the funds can be spent to hire consultants and lobbyists to shepherd lifestyle regulations through various government agencies and legislative bodies.

Some of the grants awarded in February seem clearly aimed at lobbying. In their award announcements, for example, both New York and Delaware say money will go to "educate leaders and decision makers."

The grant announcement states, at

one point, that applicants may "establish and maintain other part-time or full-time staff, contractors and consultants sufficient in number and expertise to ensure project success and have demonstrated skills and experience in coalition and partnership development, community mobilization... policy and environmental interventions...and the policies related to tobacco control."

That sounds a lot like lobbying.

Yet read further and you'll find this language: "No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any Stape or local legislature. Any activity designed to influence action in regard to a particular piece of pending legislation would be considered lob-hying."

Sowhat we have here is a \$650-million program stashed away in a major piece of legislation that funds lifestyle-change programs, despite sustained objections to anti-tobacco language (which totaled a mere \$75 million). And when the federal government went to implement the program, it told applicants that they should hire folks to build coalitions and mobilize communities — but that hiring lobby/sits was expressly forbidden.

Michelle Malkin, a conservative blogger and author, noted that the plan to devote stimulus money to try and convince smokers to quit comes at the same time the government is raising taxes on smokes to pay for health care. It seems, she said, another contradiction.

"These people can't keep their Big Nannyagendasstraight," shewrote.

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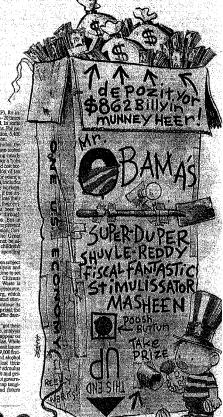
The Washington Times

Sex, drugs and **BlackBerry**s

President Obama

Money to help the private sector **asted** on government bureaucracy

president Obarna proposed assured Americans the percent stimulus package would students to the private focus recovery and growth in the private remains a sector; however, just 440,765 nonipublic lobs laive originated from ARRA funding.



The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the United States

Strategic Dialogue on Tobacco Harm Reduction Group*

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Abstract

The issues related to tobacco harm reduction continue to challenge the tobacco control research and policy communities. The potential for combusting tobacco products to reduce exposure and risk remains largely unknown, but this has not stopped manufacturers from offering such products making these claims. The role of oral tobacco products in a harm reduction regimen has also been a source of dialogue and debate. Within the last few years, major cigarette manufacturing companies have begun selling smokeless products for the first time, claiming to target current cigarette smokers. Other cigarette manufacturers are also offering smokeless products in markets around the world. The harm reduction debate has at times been divisive. There has been no unifying set of principles or goals articulated to guide tobacco control efforts. In particular, the research needs are extraordinarily high in order to drive evidence-based policy in this area and avoid the mistakes made with "light" cigarettes. This paper discusses recommendations from a strategic dialogue held with key, mostly U.S.-based tobacco control researchers and policy makers to develop a strategic vision and blueprint for research, policy, and communications to reduce the harm from tobacco for the U.S. Short- and long-term objectives are described.

Preface

For more than two years a group of tobacco control researchers, policy and communications experts participated in a process called the Strategic Dialogue on Harm Reduction (the Dialogue). The purpose of this document is to distill a wide variety of views that emerged from the Dialogue into a platform of principles for examining the future of harm reduction in the tobacco control context. Because this document reflects input almost exclusively from U.S. tobacco control experts, its application and acceptability is primarily pertinent within the United States. The intention was not to exclude input from the rich experiences of other countries. At the same time, it would be presumptuous to suggest that this document can answer the difficult questions of harm reduction in an international context. Nevertheless, we hope this document will spur other nations to examine tobacco harm reduction within their own boundaries.

Background

Most smokers in the United States want to quit [1] and a significant number have tried to quit.[2] Although research shows that with repeated attempts, smokers can successfully quit, a new generation of tobacco products has entered the marketplace in the last decade that may jeopardize these efforts. Offering promises of reduced exposure to toxicants in tobacco smoke and oral tobacco and even making implied or direct claims to reduce the risk of cancer or other diseases, these products raise important public health policy questions.

The new tobacco products that are being offered take various forms. Some use conventional means to burn tobacco, while others employ novel technologies such as computer chips and heating blades to burn or heat tobacco. Advertisements for a number of novel combustible products promise to reduce or eliminate exposure to a subset of toxicants in tobacco smoke or to reduce exposure to secondhand smoke. Increasingly, non-combustible oral tobacco products, many low in nitrosamines compared with conventional products, are being marketed with promises of tobacco satisfaction in situations (e.g., at work or at home) where smoking is not possible. However, whether they combust or not, all of these products are apparently aimed at health-concerned smokers and/or addicted smokers unable or not wanting to quit.

From a public health perspective, there is concern about tobacco products bearing unsubstantiated claims to reduce exposure and risk.[3] They have entered the marketplace without governmental scrutiny and in the absence of any independent scientific evaluation of their claims. The greatest danger is that these products may pose a significant threat to tobacco cessation and prevention efforts. Health-concerned smokers who see the claims for novel combustible products may now think that a safer cigarette genuinely exists, making them less interested or less inclined to try to quit smoking. There is the added concern that ex-smokers may start smoking again, thinking they can now safely consume tobacco products. Likewise, those who never used may initiate tobacco use with one of these new products under the assumption that a safe tobacco product exists.

In theory, the application of harm reduction principles to the tobacco control armamentarium has potential to reduce tobacco's toll. In its broadest conception, tobacco

harm reduction consists of all methods used to reduce tobacco-related morbidity and mortality. The most effective efforts to reduce harm from tobacco use are those directed at preventing initiation of tobacco use, encouraging cessation among existing users, and protecting nonsmokers from exposure to second-hand smoke. For the purposes of this report—and more generally within the field of tobacco control—we use the term "tobacco harm reduction" much more narrowly to refer to strategies that would reduce morbidity and mortality, at both the individual and population levels. *resulting from continued use of tobacco or other nicotine-containing products.

There is a very pronounced continuum of risk depending upon how toxicants and nicotine, the major addictive substance in tobacco, are delivered. Cigarette smoking is undoubtedly a more hazardous nicotine delivery system than various forms of noncombustible tobacco products for those who continue to use tobacco, which in turn are more hazardous than pharmaceutical nicotine products. [4, 5] There is potential for an ever-wider range of consumer-acceptable alternatives to the cigarette for smokers who will not otherwise cease their dependence on nicotine. With U.S. status quo trends in smoking estimated to lead to 10 million additional deaths in the next 25 to 30 years, with virtually all of these to occur among people already smoking, and with the vast majority of them motivated to reduce their risks, the primary reduction in tobacco-related death will come from increased cessation. But the intelligent application of harm reduction principles has the potential to achieve public health gains.

^{*} For other perspectives on harm reduction see Reuter P, Caulkins JP. Redefining the goals of national drug policy: Recommendations from a working group. Maer J Public Health 1995;85:1059-63; International Harm Reduction Association. What is harm reduction? (discussion paper). September 18, 2002. http://www.ihra.net/popups/articleswindow.php?id=2 (Accessed July 30, 2005); Harm Reduction Coalition. Principles of Harm Reduction. New York, New York. Available at: http://www.harmreduction.org/ (Accessed July 30, 2005); Marlatt GA. Harm reduction: come as you are. Addictive Behaviors 1996;21:779-788.

However, in the absence of public health-based regulation, there is no way to know whether the promotion of any of the new or existing products will actually reduce exposure and risk when used by smokers or increase the number of tobacco users and weaken the impact of prevention and cessation efforts. The major concern held by some public health experts is that these new products may be nothing more than a more scientifically sophisticated version of the "light" cigarette. Experts learned -- decades too late to be of any help to the health-concerned smoker who switched to "lights" -- that "lights" were deliberately designed to reduce tar and nicotine emissions when tested by smoking machines, but not necessarily when smoked by human beings, because they allowed for compensatory smoking.[6]

Worse, these so-called "light" products did not reduce the morbidity and mortality from smoking. Thirty years ago, because of the unregulated marketplace, tobacco companies controlled much of the information related to cigarette design, product performance, and consumer behavior. Well-intentioned public health officials, without the necessary scientific information, followed the industry's message and encouraged health-concerned smokers to switch to "lights".[7] Today, "lights" and "ultralights" account for nearly 85 percent of all the cigarettes sold in the United States.[8] Yet data now show little or no reduction in deaths and perhaps an increase in adenocarcinoma of the lung.[6] With today's products, we must avoid repeating the mistakes made with "lights" decades ago. That experience, and the need to look at population-level impacts, must inform our deliberations and analysis of the new generation of products purporting to reduce individual exposure or risk. We also recognize that at the time this report is

being written there exists an unregulated marketplace where the tobacco companies continue to control the information related to cigarette design and consumer behavior.

Goals and Objectives of the Dialogue Process

The topic of tobacco harm reduction is complex and, at times, contentious. No unified vision or strategy has guided research and policy. No opportunities have existed for individuals with diverse perspectives, such as researchers, policy experts, communications experts, and advocates to come together to produce a strategic vision on issues related to this area. Instead, while there is broad support for the need to regulate tobacco products, there has been a fractured and sometimes divisive debate over issues such as the appropriate role of regulation as it relates to harm reduction and, particularly, the roles of smokeless tobacco and nicotine replacement therapy (NRT) in harm reduction.

A forum was needed to identify strategies to avoid the previous mistakes with "lights" and not lose another generation of health-concerned smokers to the potentially false hope offered by the tobacco industry. Such a forum would examine ways in which effective product regulation and appropriate consumer information could lead to significant reductions in the predicted deaths and disease from tobacco use. At the same time, it was important to ensure that the public health community explored whether and/or what possible role existed for some tobacco-based products or pure nicotine containing medicinal products in a harm reduction regimen. Other pharmacological agents can also play a role in harm reduction, but in order to limit the focus or our deliberations, we considered only nicotine —containing products.

In 2005, with funding from the American Legacy Foundation and the Robert Wood Johnson Foundation, such a forum for discussion, debate, and strategic planning was created: the Strategic Dialogue on Harm Reduction (the Dialogue). The goals and objectives of the Dialogue included systematically addressing critically important aspects of the harm reduction debate including research priorities, communication methods, policy recommendations, and overarching strategic considerations. The Dialogue was launched in the spirit of attempting to build a shared blueprint that would lead to better-defined roles, responsibilities, and opportunities for collaboration between researchers, policy makers, and advocates. Although the deliberations of the dialogue were focused on the United States and we acknowledge that the application of some of our recommendations may not apply in some countries, we hope that some of these principles will have world-wide applicability.

The Dialogue Process

Four Dialogue meetings took place between December 2005 and August 2007. The participants included policy and communications experts and scientists representing different areas of expertise including toxicology, biomarkers across disease states, risk and consumer perception, nicotine addiction, behavioral pharmacology, epidemiology, and clinical sciences. (See Table 1.) They also had differing views on tobacco harm reduction. At the initial meeting, key questions emerged that guided the work of the Dialogue and the end product, this report. Additional participants and areas of expertise were identified for inclusion in subsequent meetings. At the final Dialogue meeting, this report was reviewed and all participants had the opportunity to comment on each of the

multiple drafts of the final report. This vision and the report were endorsed by all the members of the group and the report is being released as the collective vision of Dialogue participants.

The strategic goal of the Dialogue process was to discuss the development of a long-term vision for tobacco harm reduction and short-term policy objectives to begin the lengthy process of achieving the shared long-term vision. Discussion of these short-term objectives yielded an identification of key issues to research in order to properly evaluate all products in the tobacco marketplace. Research will also help to determine the feasibility and potential impact of the proposed long-term vision.

The Policy and Regulatory Context

The Dialogue process took place when -- for the first time -- there were legitimate prospects for comprehensive tobacco product regulation. Globally, the Framework Convention for Tobacco Control mandates such regulation.[9, Article 9-11] In the United States, legislative efforts have been mounted to give regulatory authority over tobacco products to the Food and Drug Administration (FDA).[10] FDA had previously asserted jurisdiction over tobacco products in the mid-1990s, but that action was overruled by the Supreme Court in 2000.

Effective product regulation has the potential to be an important complement to the evidence-based policy interventions already in place that have helped drive down U.S. tobacco use over the past 40 years. These existing policies include proven prevention programs such as aggressive counter-marketing efforts, encouragement of use and provision of cessation products and services to help tobacco users quit, legislative initiatives to raise excise taxes, implementation of comprehensive smoke-free air laws.

restrictions on tobacco marketing, stronger and more visible graphic warning labels, and improvement of access to treatments for tobacco dependence.[9, 11] The primary goal of product regulation would be to reduce morbidity and mortality associated with the use of tobacco products.

The Long-Term Vision and Short-Term Policy Objectives of the Strategic Dialogue on Harm Reduction

Throughout the Dialogue process, participants engaged in a discussion and exploration of key principles to guide a unified approach to dealing with issues surrounding harm reduction. The following four principles were identified as an essential foundation for subsequent discussions and recommendations:

- The primary goal of tobacco control is to reduce mortality and morbidity associated with tobacco use.
- "Tobacco-free" should be the norm. Policy interventions such as clean indoor air laws, sustained media campaigns, and excise tax hikes, coupled with expanded prevention and treatment efforts, should continue to be at the forefront of tobacco control efforts to denormalize tobacco use.
- Achieving the primary goal might entail continued use of selected nicotinecontaining products if doing so would deter the use of more toxic tobacco products and would result in a significant reduction in tobacco-related morbidity and mortality.
- 4. Any company marketing nicotine-containing products needs to be accountable for the toxicity of its products and must bear the burden of proof for any product claims. There needs to be an adequate science base to support claims, and they must be truthful and not misleading.

If the primary goal of tobacco control is to eliminate morbidity and mortality associated with the use of tobacco products, the most effective means is abstention from all tobacco products. This was judged to be a population outcome that would take time to accomplish. In this context, Dialogue participants with differing views on the role of smokeless tobacco use in harm reduction were able to reach a consensus on one long-

term vision: a world where virtually no one uses <u>combustible</u> tobacco products. This is not a recommendation to ban cigarettes and embrace a policy of prohibition, nor does it reflect any agreement about recommending that smokers switch to smokeless tobacco products. Rather, it is a clarion call to alter the current marketplace to reduce the number of people who use cigarettes. Given the currently widespread use of combustible tobacco products, this is obviously a highly ambitious long-term vision, subject to controversy and skepticism regarding its feasibility.

Dialogue participants also identified two key short-term policy objectives to help achieve the primary goal of reducing the morbidity and mortality from tobacco by reducing tobacco use and the number of tobacco users. These are:

- 1. Establish effective public health-based regulatory control of all tobacco products.
- 2. Shift current tobacco users who are unable or unwilling to become nicotine free toward the least harmful products, i.e., medicinal nicotine.

Rationale for the Long-Term Vision Where No One Uses Combustible Tobacco Products

A world in which no one uses combustible tobacco products would have a profound impact on reducing death and disease from tobacco use. Perhaps in response to the prospect of significant reductions in tobacco use, tobacco product manufacturers have introduced many new products known as Potential Reduced Exposure Products [PREPs; 3] with the dual goals of appearing to address the health concerns of smokers while simultaneously maintaining overall tobacco use.

The discussions and controversies evolving around the recent introductions of PREPs have led to a closer examination of the health risks associated with all tobacco products. This examination has caused many to conclude that combustible PREPs are

unlikely to significantly contribute to a reduction in the death and disease from tobacco use.[4, 5, 12-15]

How to determine the likely reduction in individual-level risk and population-level harm across various PREPs is still an open scientific question. Research in several areas is being conducted to evaluate the following factors as potential determinants: (1) toxic constituents in tobacco products and smoke emissions, (2) preclinical cytotoxicity and genotoxicity in cell cultures and animal models for toxicity and disease, (3) biomarkers of exposure and effect in humans, and (4) actual health outcomes across various morbidity factors. The convergence of the results in all these areas of testing is likely to constitute the evidence base for determining the reduced risk potential of a product, with the ultimate evaluation criteria resting on actual health outcomes.

Because of the many years that would be required to directly observe the health effects of a PREP, evaluation currently relies on shorter-term clinical and laboratory measurements, including assessment of toxic chemical delivery, biomarkers of exposure, and biomarkers of effect. Toxic chemical delivery is a measure of the level of chemical constituents of concern to which a user of the product is exposed. Usually these measurements are carried out using external devices that smoke or extract the chemicals of concern before analysis of their amounts. Preferably, the delivery process is designed to mimic how people use the product; however, all too often this has not been the case and has led to false estimates of exposure.[6, 16] This is also complicated because of both intra- and inter-individual variability in product use. Biomarkers of exposure measure a "constituent or metabolite of the product that is obtained in biological fluid or tissue." Biomarkers of effect refer to "a measured effect including early subclinical

biological effects, alterations in morphology, structure or function; or clinical symptoms consistent with the development of health impairment and disease".[17] To date, a few clinical trials that have used these biomarkers suggest that there is a spectrum of potential harm across different types of tobacco or nicotine-containing products, [4, 18, 19] with the greatest harm associated with the conventional combustible tobacco products and the least harm associated with therapeutic nicotine replacement products.

Based on current knowledge, novel combustible products are unlikely to substantially reduce risk for disease because of the number of toxic combustion constituents associated with cigarette smoke. Human studies on modified, reduced-toxicant cigarette products have shown only moderate or modest reductions of some toxicants, no significant reductions of other toxicants, and even some increases in other toxicants.[20-23]

Some have concluded that a cigarette product that may lead to significant reduction in risk is one with a nicotine content that is too low to promote initiation, sustain addiction, or lead to compensation.* The harm reduction potential from such a product is not a consequence of a reduction in toxic constituents, but rather a reduction in the addiction potential of the product. A gradual reduction in the nicotine content of all cigarettes was proposed in 1994 by Benowitz and Henningfield.[24] This approach could theoretically lower the prevalence of smoking by reducing initiation by adolescents and increasing abstinence rates among addicted adult smokers.

^{*} Compensation occurs when smokers engage in behaviors to defeat product modifications such as lowered nicotine content. Such compensatory behaviors include smoking more cigarettes, taking more puffs, or taking larger puffs. [6] National Cancer Institute. Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute 2001.

Preliminary evidence has suggested that smokers using specially designed test cigarettes with lowered nicotine content in the tobacco show a dose-related reduction in nicotine intake, with only modest compensation.[25, 26] This finding points to the potential feasibility of reducing nicotine addiction through reduced-nicotine cigarettes. The test cigarettes used are different from the commercial "low-yield" cigarettes that have similar levels of nicotine as the higher yield cigarettes but achieve lower machine-determined yields due to ventilated filters. Ventilated filters have one or more rings of small perforations that allow air to dilute smoke, thereby reducing machine-based yields of tar, nicotine, and carbon monoxide.[6] Unlike machines, smokers can achieve higher levels of nicotine by smoking harder on a cigarette and/or blocking the ventilated filters.[6]

Considerable research needs must be addressed before the nicotine reduction approach can be recommended. Reducing the nicotine content in cigarettes should be pursued only if it reduces smoking prevalence and does not lead to a significant increase in toxicant exposure in continuing smokers due to compensatory smoking. It should also only be considered in a regulated environment where addicted adult smokers would be provided easily accessible products, programs, and services to stop using cigarettes.[27]

The State of the Science on Other Tobacco and Nicotine-Based Products

Cigarette-like delivery devices that heat rather than burn cigarettes, such as Philip Morris' Accord and Reynolds American Inc.'s Eclipse, are being sold in the United States and other countries. To date, there have not been sufficient studies of these products to determine their value in reducing exposure and disease. The results from

studies conducted by Roethig and associates, testing one of the cigarette-like delivery devices, showed significantly lower levels of some carcinogen-related toxicants compared with conventional combustible products in both residential and non-residential settings and in short and long-term trials.[28-31] One study also showed significant improvements in some of the cardiovascular risk factors that were measured.[30] To date, it is unknown if the extent of the observed reductions and if reductions in some but not all biomarkers would lead to relative reductions in disease risk compared to continued smoking on conventional cigarettes. Furthermore, not all of these devices are alike. For example, in studies with another electronically heated cigarette-like device, significant increases in some of the biomarkers of exposure and effect were observed.[see 18, 32]

On the continuum of risk, non-combustible tobacco products are more likely to reduce harm than a smoked form of tobacco for individuals who would otherwise be using conventional cigarettes. Though Dialogue participants did not fully agree on the role of smokeless tobacco products as a harm reduction agent, there was a consensus about the value and the concept of this continuum of risk.

To reduce harm, these non-combustible nicotine-containing products will need to expose users to significantly fewer and lower levels of toxicants than cigarettes, and their use should not discourage or delay quitting combustible products. Any discussion of the harm reduction potential of smokeless tobacco products must take into account a series of individual and population-level policy issues including (1) the relative toxicity and risks of any oral tobacco products compared with cigarettes; (2) concomitant use of oral tobacco products and cigarettes with the potential for increased exposure to toxicants; (3) increased prevalence of oral tobacco use due to increased uptake among those who would

otherwise never use tobacco, maintenance of oral tobacco use in consumers who would have otherwise quit, and/or relapse to tobacco use; and (4) potential as a gateway product to or from cigarette smoking.[See, for example, 19, 33, 34, 35]

Smokeless tobacco companies and cigarette manufacturing companies in the United States are marketing reduced-toxicant (lower tobacco-specific nitrosamines, TSNAs) and spitless oral tobacco packets or lozenges. Some of these newer U.S. products are lower in TSNA levels than some conventional and most popular brands of smokeless tobacco sold in the United States or in other parts of the world such as India and comparable to or lower in TSNAs than the smokeless tobacco products sold in Sweden.[19, 36, 37] One study showed that tobacco carcinogen exposure (NNK) can be reduced when smokers switch to smokeless tobacco products;[38] however, human clinical studies on the effects of oral tobacco products on biomarkers of exposure and effect are limited.

Smokeless tobacco has been found by the U.S Surgeon General, the American Cancer Society and IARC to be a cause of oral cancer and possibly pancreatic cancer [39]. Nonetheless, if smokers who cannot or will not quit their dependence on nicotine switched completely to smokeless tobacco products, they would likely experience a reduction in tobacco-caused mortality and morbidity. The extent of this reduction is unknown. Nevertheless, these persons would not be risk-free, and their risk would be higher than if they switched to medicinal nicotine.

Several published reports and articles describe a significantly lower risk for disease from using smokeless tobacco compared with cigarettes.[e.g. 5, 19, 34, 40]

Unlike cigarette smoking, smokeless tobacco use has not been linked to many of the smoking-related cancers [39] or to pulmonary disease.[41]

Interestingly, those who believe that smokeless tobacco can be used to reduce population-level harm caused by tobacco and others who challenge these claims as unproven have both cited the so-called "Swedish experience." Those who contend that the Swedish experience supports the use of smokeless tobacco for harm reduction cite studies that have found, for example, that rates of lung cancer in men in Sweden were significantly lower than the rates found in men in Norway, which has higher rates of cigarette smoking. Authors of those studies attributed this dramatic reduction in lung cancer to increased prevalence of consumption of snus, Sweden's low-nitrosamine form of smokeless tobacco, which was associated with and may have led to reduced prevalence of cigarette smoking.[42] A study conducted in Sweden with males in a twin study observed that the use of the form of snus sold in Sweden was associated with smoking cessation but not initiation,[43] suggesting to the authors that there were no adverse effects of snus on smoking prevalence and smoking-induced disease. Further, proponents of the use of snus for harm reduction point to studies that demonstrate that snus switchers achieve greater health gains compared with smokers who did not switch, and similar gains to those who quit all tobacco products.[44] It is important to keep in mind that the Swedish studies were conducted in an environment with stronger tobacco regulation that included an advertising ban. Some experts question whether these results, even if widely accepted, are generalizable to other countries.

Other researchers have pointed to other tobacco control factors that may have led to reduction in lung cancer rates in Swedish men and which may have contributed to the

low smoking prevalence rates in places such as California.[e.g., 45, 46] Tomar [45] also notes that some U.S. states have high rates of smokeless tobacco use without a corresponding reduction in the prevalence of cigarette smoking. This finding is likely to be true in a culture that aggressively markets both cigarettes and smokeless tobacco products. Furthermore, unlike the switchers to snus products, in one study smokers who switched to U.S. smokeless tobacco products were found to be at greater risk for mortality compared with smokers who quit completely.[47]

The safest nicotine-based products are likely to be therapeutic nicotine products such as the gum, patch, and lozenge. They contain nicotine but none of the other toxicants found in tobacco. These products are not considered absolutely safe because of the risk for fetal toxicity and increased levels of cardiovascular risk factors, such as effects on blood lipids, endothelial dysfunction, and insulin resistance.[48, 49] Still, these products are less hazardous than tobacco products. Medicinal nicotine and other approved products are at a significant marketing disadvantage compared to tobacco products. They must undergo a rigorous federal approval process and are designed to minimize addiction. By contrast, tobacco products are currently subjected to no product regulation.[50]

To facilitate a transition of smokers from the most toxic to the least toxic form of nicotine delivery, consideration should be given to looking at the nicotine market as a whole and developing a more coherent policy that explores the impact of promoting the use of the least toxic forms of nicotine delivery and discourage the most toxic forms. This should include the possibility of making the therapeutic nicotine products more consumer acceptable and effective.[51] Technically, this can be done by making the

products more palatable through improved taste and sensory perception, and by increasing the amount and the delivery speed of nicotine.[4] However, the health and behavioral risks of a pure nicotine delivery that has these characteristics are unknown and require study; although the occurrence of greater health risks, with the exception of long term or dependent use, seems unlikely.

In summary, the consensus among Dialogue participants and other researchers [5] is that the use of combustible tobacco products will always pose the greatest risks. The tobacco harm reduction approach that will lead to the greatest reduction in tobaccorelated morbidity and mortality is cessation of use of all tobacco products. Short of this goal, shifting from combustible tobacco products to the long-term and exclusive use of non-combustible products, particularly therapeutic products, with the right controls and post-market surveillance is likely to create less harm among continuing users. This shifting of product use should be part of a comprehensive approach that includes the regulation of all nicotine products, whether or not they contain tobacco. For cigarette users who switch to smokeless tobacco products, maximal potential reduction in harm could only occur with products that result in the lowest exposure to toxicants, are subject to government regulation, and that avoid adverse consequences such as increased initiation of tobacco use or decreased cessation.

Key Elements to Achieve Short-Term Policy Objectives

Dialogue participants identified two short-term policy objectives in addition to prevention and cessation likely to achieve harm reduction as defined in this report: (1) effective tobacco product regulation, and (2) promoting a shift by tobacco users toward

the least harmful products, i.e., medicinal nicotine. Product regulation is a critical component in the efforts to reduce harm associated with tobacco use and is a mechanism to facilitate the long-term vision of the Dialogue, where no one uses combustible tobacco products. As stated in the 2001 Institute of Medicine (IOM) report, <u>Clearing the Smoke</u>, "Regulation of all tobacco products...is the necessary basis... for assuring that the health of the public is protected".[3, page 6]

Dialogue participants reached a consensus on a series of key elements in a regulatory scheme for tobacco products. The regulatory tools that have been recognized by the World Health Organization Study Group on Tobacco Product Regulation (TobReg, http://www.who.int/tobacco/global_interaction/tobreg/tsr/en/index.html) and in the legislation pending in the U.S. Congress in 2008 that would grant regulatory authority over tobacco products to the Food and Drug Administration provide useful guidance.[10] The consensus regulatory elements include:

- a) Disclose all known toxicants to regulatory agencies. Disclosure of the type and amount of all toxicants in tobacco products by brand and brand subtype is not currently required from tobacco companies, although most other consumer products are subject to such requirements. Disclosure of all toxicants would serve several functions: (1) educating public health officials and policymakers about the types and relative amounts of toxicants contained in tobacco products, (2) providing a basis for monitoring toxicants in tobacco products by the government, and (3) establishing a platform for regulating these toxic constituents. Regulators would have to make a science-based decision on whether and how this information should be disclosed to consumers.
- b) Identify toxicants targeted for reduction. Toxicants should be identified based on whether they are known to cause adverse effects and the extent to which they are linked to tobacco-related disease and/or addictive behavior.[3] The World Health Organization Committee on Tobacco Product Regulation (TobReg) has been working to identify known emissions toxicants that should be reduced in cigarette products. Toxicants were identified by TobReg based upon their carcinogenic and toxic activities, their known effects in humans, and their concentrations in cigarette smoke. The toxicants identified by TobReg for regulation are acetaldehyde, formaldehyde, benzene, 1,3-butadiene, acrolein, benzo[a]pyrene,

carbon monoxide, NNN, and NNK. Several other toxicants were also recommended as candidates for reporting to governments.[52] They are acrylonitrile, 4-aminobiphenyl, cadmium, catechol, crotonaldehyde, hydrogen cyanide, hydroquinone, 2-naphthylamine, and nitrogen oxides. As products and science evolve, these targeted toxicants will need to be revisited.

c) Develop a science-based rationale for reducing toxicants in all tobacco products. Cigarettes and smokeless tobacco products vary tremendously in their toxicant levels. This is a function of the type of tobacco leaves in the product, the curing and manufacturing processes, and how the products are consumed. For example, the variability in tobacco-specific nitrosamines -- a potent carcinogen -- can range over a 20-fold difference in cigarettes worldwide [53] and greater than a 48-fold difference among U.S. oral tobacco products.[0.19 to 9.2 µg/g product wet weight, 36] Although no studies have been conducted on the relationship between tobacco-specific nitrosamine levels in different brands of cigarettes and uptake of these carcinogens in humans, preliminary results in an experimental setting show a relationship with smokeless tobacco products.[19] Therefore, depending on factors the preliminary tests did not examine, it may be that reducing levels of toxicants in smokeless tobacco products can potentially result in reduction of exposure to these toxicants.[23, 54] Smokeless tobacco products (snus) in Sweden tend to be lower in tobacco-specific nitrosamines and other toxicants compared with the most popular brands in the United States, primarily because the Swedish tobacco companies have self-imposed performance standards. As a result, in Sweden there are studies that conclude that the risk for disease associated with snus tends to be lower, particularly in contrast with risk for disease observed in India and the United States, where the smokeless tobacco products tend to have higher levels of toxicants.[19]

Because of nicotine's role in cigarette use,[55] reducing levels of toxicants without taking into account nicotine levels may not lead to significant reduction in toxicant exposure. In the case of higher ventilation cigarettes, both machine-measured tar and nicotine were reduced over the past 30 years and, as a consequence, smokers increased their intake of toxicants per cigarette to compensate for the reduced levels of nicotine.[6] Reducing toxicants on a per-milligram-of-nicotine basis, as proposed by TobReg, may circumvent this problem, although no proof of concept study has been conducted. Furthermore, measures must be taken to ensure that nicotine yields are not increased in cigarettes in order to maintain a specified toxicant-to-nicotine yield ratio. While increasing nicotine levels might reduce the number of cigarettes smoked and lead to reduced exposure,[56] this method may increase the number of tobacco users addicted to their product. Any adjustment of nicotine levels – up or down – requires careful study and monitoring and should only be done in a regulated environment.

d) Establish a standard for the maximum level of specific toxicants and prohibit the sale of tobacco products that exceed the established standards. Although Dialogue participants were not asked to endorse the quantification of toxicant

reduction during the Dialogue process, it is important to note that performance standards should be determined by a body of experts independent of the tobacco companies and that Gray et al.,[4] commented that the performance standards can become more stringent over time. At this point, there are no mandatory performance standards in the United States or globally, thus leaving the companies free to deliver any level of toxicants they choose. Once in place, tobacco companies should not be allowed to publicize mere compliance with any such standards.

- e) Establish a standard for nicotine yields across tobacco products. This regulatory approach would prevent tobacco companies from independently increasing nicotine in tobacco products, as has been observed over several years in a study conducted by the Harvard School of Public Health.[57] Furthermore, it would give regulatory authorities the power to alter levels of nicotine in tobacco products based upon the best available science.[24, 27, 58]
- f) Assess the human exposure impact for toxicant reduction. The recommendations to develop performance standards must remain fluid. Determination as to whether the proposed standards result in exposure reduction must be based on evidence from human clinical exposure trials and will evolve from data produced by the tobacco companies and by independent scientists. Results from studies may necessitate revisions to previously established performance standards.
- g) Prohibit exposure reduction claims associated with reductions in level of toxicants. Exposure reduction claims are likely to mislead consumers into thinking that a product is "safer" or "safe".[59, 60] This is one of the lessons learned from the experience with "light" cigarettes.[61-65] Until there are data to demonstrate that specific levels of toxicant exposure lead to reduction in risk at the population level, tobacco companies should not be allowed to make exposure reduction claims alone. Post-marketing surveillance of any approved risk reduction claims will be necessary to determine the impact of these claims on initiation, relapse, cessation, and health.
- h) Educate the public about exposure vs. risk reduction. Regulation of tobacco products, and efforts to reduce toxicant levels in tobacco products could lead the public to perceive the tobacco products as "safer" or "safe" or "endorsed" by the government. A well-designed public education program, grounded in science-based information, needs to be developed. It should include media campaigns that explain the differences between exposure and risk reduction and emphasize the benefit of total cessation of tobacco use.
- Regulate the promotion, advertising, and labeling of tobacco products. The goal
 of this regulation is to prevent false or misleading claims, implied or direct.
 Studies will be needed to provide the evidence base for a proper evaluation of
 promotion, advertising, and labeling.

j) Establish research priorities to achieve regulatory elements a-i. Research needs for the assessment of PREPs and tobacco products in general have been clearly described in other reports and articles.[3, 34, 66] These include development of (1) animal models and in vitro assays of the pathogenesis of tobacco-attributable diseases; (2) human biomarkers of exposure and effect and the relationship between these biomarkers with disease risk; (3) methods and measures for short-term clinical and epidemiological studies, including consumer perception testing; and (4) post-marketing surveillance or long-term studies to determine the impact of PREPs on a population level.

Research is needed to provide guidance for regulation addressing such issues as (1) whether and how to best educate consumers about the toxicant level in tobacco products so that an informed decision can be made on product use or choice of products and so the consumer is not misled; (2) the impact of reducing toxicants on machine-determined yields and in preclinical (animal and *in vitro* assays) and clinical human exposure studies; (3) the process, impact, and viability of gradually reducing nicotine yields of tobacco products, particularly in conjunction with reducing toxicant yields per milligram of nicotine; and (4) the best way to educate the public on reduced exposure vs. reduced risks and on relative risks, without compromising public health. In all these research questions, the effects on a heterogeneous population (e.g., gender, racial/ethnic, SES, tobacco use status, concern about health, motivation to quit) must be considered.

To shift the population who cannot or will not quit altogether toward the use of the least harmful products (the second short-term policy objective), a number of methods were identified for further exploration. These were:

- a) Substantially raise the tax on combustible tobacco products on a regular basis over time. Increasing the cost of the most dangerous compared to the least dangerous products (e.g., medicinal nicotine) can switch preferences toward the less costly products. For example, studies have been conducted with unhealthful vs. healthful food products in schools and worksites in which low-fat, low-calorie foods were priced lower than high-fat, high-calorie foods.[67] An increase in intake was observed for the more healthful foods with a decrease in consumption of less healthy foods.
- b) Institute different levels of availability and packaging based on risk in accordance with a system established by an independent regulatory agency. More toxic products should be made less available. For example, tobacco products could be placed below the counter at retail outlets, completely out of view of the public, especially from children and adolescents. In addition, research on label statements should be conducted to more effectively communicate relative toxicity (e.g., tobacco products vs. medicinal products).

- c) Consider providing appropriate incentives and/or disincentives for manufacturers. No company should be able to make an exposure reduction claim. However, if there is a documented decrease in risk, it may be possible to create appropriate incentives. These could include granting a "pioneer" company a period of time where it has exclusive use of an approved claim, or ordering mandatory cross-licensing of technologies that have been proven to reduce exposure and risk with royalty payments guaranteed to the "pioneer." This could create a financial incentive for innovators of genuinely reduced-risk products. Other potential financial incentives should be explored.
- d) Expand anti-tobacco advertising, label all cigarettes as deadly and addictive, and educate the public accurately on the precise risks of different products. All of these steps should be taken in a regulated environment. The third of these recommendations stems from the principle that consumers deserve accurate and evidence-based information on the toxicity and relative risk for disease of different products.[68] For example, the public has misconceptions that medicinal nicotine products are associated with risks for certain tobacco-caused diseases that should be corrected. [61, 69, 70]
- e) Strong messages and programs for cessation of all tobacco products. No tobacco product should be considered safe. Tobacco users who are unable or unwilling to quit tobacco should be encouraged to move toward the least hazardous form of nicotine delivery available, therapeutic nicotine products, or other therapeutic products for cessation. Cessation programs and products should be universally available and widely promoted.
- f) Establish research priorities to achieve elements a-e. The critical research questions to address for these short-term policy recommendations are the following: (1) the relative risk across different types of tobacco products and methods to determine relative risk; (2) a better understanding of the relationship between increasing the cost of a highly toxic product and consumers' decisions to switch to less toxic products; (3) optimal methods to educate the public and to correct consumer misperceptions about the relative risk of products; and (4) the population impact of the proposed measures on increasing initiation or decreasing cessation.

Three additional initiatives were identified by Dialogue participants as worthy of

further exploration and research.

 Explore whether reducing nicotine exposure in combustible products to nonaddicting levels is likely to lead to a reduction in smoking prevalence; accounting for the potential unintended consequences of such a strategy, including whether such a step would result in the creation of a black market for higher nicotine cigarettes.

- Explore the effects of low-toxicant smokeless tobacco products as a harm reduction tool, and determine the safety and impact, on individual and population levels, of informing the public about the relative risk of oral tobacco products compared with combustible tobacco products.
- 3. Explore issues surrounding long-term use of nicotine at the population level; account for the trade-offs that may be inherent in this approach, such as a reduction in overall disease toll but an increase in initiation or persistence of nicotine use due to the knowledge that a "safer" alternative exists.

Finally, the following significant <u>infrastructure needs</u> were identified by Dialogue participants:

- a) Enhanced surveillance of tobacco product use. Surveillance to assess population impact (e.g., rates of initiation and cessation, and concurrent product use) is a critical component to achieve a short-term rapid response capability that will support the long-term vision of the Dialogue. As described in several publications, [3, 66] both short-term and long-term continuous surveillance is critical to assess the patterns of tobacco use and impact of policies and products on health outcomes. Surveillance should include an assessment of biomarkers of tobacco toxicant exposure in individuals using different products and whether there is any correlation between those measurements and health outcomes.
- b) Creation of a research consortium. In the United States, this would ideally include relevant government agencies -- the Centers for Disease Control and Prevention (CDC), Environmental Protection Agency (EPA), National Institutes of Health (NIH) -- and a range of private and academic research facilities for product testing, human exposure studies, and consumer perception studies. The CDC can contribute its expertise in product testing, toxicology, and surveillance; the EPA can contribute hazard identification, risk assessment, and risk management; and the NIH can generate the research base for addressing critical questions about viable and effective methods for tobacco harm reduction. The contracted research centers would be composed of a consortium or network of independent scientists and testing facilities to test tobacco products using animal and human protocols. This research consortium would closely interact with international efforts in this area, including WHO's Committee on Tobacco Product Regulation and Tobacco Laboratory Network initiatives.

Summary and Conclusions

Dialogue participants reached a consensus that, based on the currently available evidence, significant tobacco harm reduction can be achieved over the long term only in a

world where virtually no one uses combustible tobacco products. In such a world, smokers would either quit completely or switch to the least harmful form of nicotine delivery, i.e., medicinal nicotine. Steps toward achieving this ambitious vision would include policies that discourage the use of combustible products through taxation and access, marketing, and promotion. It might also be possible over time to employ product regulation to permit the sale only of nonaddicting combustible tobacco products so that young people who experiment with cigarettes would not become addicted.

Decreasing tobacco initiation and increasing tobacco cessation are proven harm reduction strategies. Current efforts in these areas are woefully underfunded.

Implementing the recommendations of the recent IOM report [11] to fully fund comprehensive tobacco prevention and control funding at CDC-recommended levels is a required first step. Tobacco product regulation is also needed to provide a mechanism to reduce the harmfulness of tobacco products. In a regulated environment:

- Tobacco constituents and additives should be disclosed to and monitored by regulatory agencies.
- b) Performance standards should be established so that all tobacco products would have maximum limits on nicotine and toxic tobacco constituents and emissions.
- c) Exposure reduction claims should be prohibited in the absence of adequate evidence of risk reduction. Mechanisms should also ensure that claims are examined based on the impact on the population as a whole as well as individual consumers.
- d) Risk reduction claims should have an adequate scientific base, including evidence of anticipated population-level effects (e.g., on initiation and cessation).

- e) Any risk reduction claims should be evaluated and approved by a regulatory agency on a pre-market basis.
- f) Post-marketing surveillance should be used to re-evaluate the claims.
- g) Consumers should be accurately informed and educated about relative risks of the use of different types of nicotine containing products.
- h) Combustible products that reduce nicotine exposure to non-addictive levels should be investigated.
- Individual risk and population health impacts of long-term use of nicotine-only products should be examined.
- j) Policies that shift the population to less harmful products should be explored taking into account their impact on prevention and cessation efforts and overall tobacco-related mortality.
- k) The effects of regulatory policies on prevalence of tobacco use and tobaccocaused mortality and morbidity should be monitored.

In the short term, the following action steps need to be taken: (1) Pass effective legislation for tobacco product regulation, (2) develop the proposed infrastructure and network for product testing and scientific inquiry, (3) coordinate national and international efforts, and (4) address the research questions necessary to determine the feasibility and impact of fulfilling the long-term vision. Much is already known about the building blocks required to achieve the long-term vision and short-term policy objectives identified by the Dialogue. What is missing is the requisite degree of public and political support to dare to envision a future world where almost no one uses a combustible tobacco product.

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Table 1

Strategic Dialogue on Tobacco Harm Reduction Participants*

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Neal Benowitz, M.D., University of California, San Francisco, CA
Lois Biener, Ph.D., University of Massachusetts, Boston, MA
David Burns, M.D., University of California, San Diego, CA
Pamela Clark, Ph.D., Battelle Center for Public Health, Baltimore, MD
Greg Connolly, D.M.D., M.P.H., Harvard School of Public Health, Boston, MA
Mirjana Djordjevic, Ph.D., National Cancer Institute, Bethesda, MD
Thomas Eissenberg, Ph.D., Virginia Commonwealth University, Richmond, VA
Gary Giovino, Ph.D., University at Buffalo, SUNY, Buffalo, NY
Dorothy Hatsukami, Ph.D., University of Minnesota, Minneapolis, MN (Dialogue co-chair)

Cheryl Healton, Ph.D., American Legacy Foundation, Washington, DC

Stephen Hecht, Ph.D., University of Minnesota, Minneapolis, MN

Jack Henningfield, Ph.D., Pinney Associates, Bethesda, MD

Corinne Husten, M.D., M.P.H., Partnership for Prevention, Washington, D.C. (during the Dialogue process, Dr. Husten was with the Centers for Disease Control and Prevention, Atlanta, GA)

Kimberly Kobus, Ph.D., University of Illinois, Chicago, IL
Scott Leischow, Ph.D., University of Arizona, Tucson, AZ
David Levy, Ph.D., Pacific Institute for Research & Evaluation, Calverton, MD
Stephen Marcus, Ph.D., National Cancer Institute, Rockville, MD
Matthew Myers, J.D., Campaign for Tobacco-Free Kids, Washington, DC
Mark Parascandola, Ph.D., National Cancer Institute, Rockville, MD
Prabhu Ponkshe, Health Matrix Inc., McLean, VA
Peter Shields, M.D., Georgetown University, Washington, DC
Paul Slovic, Ph.D., Decision Research, Eugene, OR
David Sweanor, J.D., University of Ottawa, Ottawa, Ontario
Kenneth Warner, Ph.D., University of Michigan, Ann Arbor, MI

Mitchell Zeller, J.D., Pinney Associates, Bethesda, MD (Dialogue co-chair)

*Dialogue members participated in their individual capacity. Organizational affiliations are provided for informational purposes only. The views expressed here are those of the authors only and do not represent any official position of the National Cancer Institute or National Institutes of Health.

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Appendix 1. Strategic Dialogue on Tobacco Harm Reduction Participants
Financial Disclosure Responses*

Cathy Backinger, Ph.D., M.P.H.	No conflicts of interest
Neal Benowitz, M.D.	Serves as a paid consultant to several pharmaceutical
, , , , , , , , , , , , , , , , , , , ,	companies that market or are developing smoking cessation
	medications. Also serves as a paid expert witness in
	litigation against tobacco companies.
Lois Biener, Ph.D.	No conflicts of interest.
David Burns, M.D.	Testified against the tobacco industry in multiple lawsuits
Pamela Clark, Ph.D.	No conflicts of interest.
Greg Connolly, D.M.D., M.P.H.	No conflicts of interest.
Mirjana Djordjevic, Ph.D.	No conflicts of interest.
Thomas Eissenberg, Ph.D.	Consulted with the National Association of Attorney's
	General on issues related to PREPs and PREP testing.
	Received free of charge smokeless tobacco products from
	R.J. Reynolds to test them in his laboratory. Neither R.J.
	Reynolds nor any other company has ever had any input
	into any work done in his laboratory nor have they had any
	input into any reporting of results.
Gary Giovino, Ph.D.	No conflicts of interest.
Dorothy Hatsukami, Ph.D.	Consulted for pharmaceutical companies (Pfizer, Abbott)
	that are marketing or developing smoking cessation
	medications. No honorarium received. Received research
	grant from Nabi Biopharmaceuticals for clinical trial.
Cheryl Healton, Ph.D.	No conflicts of interest.
Stephen Hecht, Ph.D.	Served as an expert witness for the plaintiff in a case in
	which United States Smokeless Tobacco Company is being
	sued by the family of a man who died from oral cancer after years of using smokeless tobacco.
Jack Henningfield, Ph.D.	Pinney Associates provides consulting services to
Jack Henningheid, Fu.D.	GlaxoSmithKline Consumer Healthcare on issues related to
	treating tobacco dependence. Has interest in a nicotine
	delivering smoking cessation product under development.
Corinne Husten, M.D., M.P.H.	Owns pharmaceutical stock (Johnson and Johnson, Pfizer).
Kimberly Kobus, Ph.D.	No conflicts of interest.
Scott Leischow, Ph.D.	Consultant/Advisory Committee member, speaker for Pfizer
, , , , , , , , , , , , , , , , , , , ,	Pharmaceutical Company; consultant for Johnson and
	Johnson
David Levy, Ph.D.	No conflicts of interest
Stephen Marcus, Ph.D.	No conflicts of interest
Matthew Myers, J.D.	No personal conflicts of interest. The Campaign for
	Tobacco-Free Kids has received donations from
	pharmaceutical companies that make cessation products.

	albeit those donations are a very small percentage of the Campaign's budget
Mark Parascandola, Ph.D.	No conflicts of interest
Prabhu Ponkshe	No conflicts of interest
Peter Shields, M.D.	Served as expert witness in tobacco litigation.
Paul Slovic, Ph.D.	No conflicts of interest
David Sweanor, J.D.	Receives, directly or indirectly, fees from the marketers of smoking cessation medicines. None of this money is significant enough in relation to his personal financial resources to be considered material.
Kenneth Warner, Ph.D.	Chair of the Pfizer Tobacco Independence Global Policy Advisory Board, for which an honorarium is received (which is immediately endorsed to my School to a scholarship fund).
Mitchell Zeller, J.D.	Pinney Associates provides consulting services to GlaxoSmithKline Consumer Healthcare on issues related to treating tobacco dependence.

QUESTIONS SUBMITTED FOR THE RECORD HEARING ENTITLED, "SMOKELESS TOBACCO: IMPACT ON THE HEALTH OF OUR NATION'S YOUTH AND USE IN MAJOR LEAGUE BASEBALL" SUBCOMMITTEE ON HEALTH COMMITTEE ON ENERGY AND COMMERCE UNITED STATES HOUSE OF REPRESENTATIVES APRIL 14, 2010

Terry F. Pechacek, Ph.D.
Associate Director for Science, Office on Smoking and Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

The Hon. Edward Whitfield

1. What evidence did the CDC rely upon to award a grant for \$977,346 so smokers in the District of Columbia could receive a free blackberry?

Funding for the Blackberry phones was not provided by the Centers for Disease Control and Prevention (CDC) and is not part of the Communities Putting Prevention to Work program. CDC's understanding is that funding for these phones came from the Schroeder Institute for Tobacco Research and Policy Studies, supported by the American Legacy Foundation.

2. Have any studies been published in a peer reviewed journal demonstrating the effectiveness of such a program?

CDC has not undertaken studies in this area. This is an emerging field and there is not a great deal of evidence available. However, the National Cancer Institute at the National Institutes of Health has sponsored some studies on the topic, including:

- Obermayer JL, Riley WT. Asif O, Jean-Mary J. College smoking-cessation using cell phone text messaging. J Am Coll Health. 2004 Sep-Oct;53(2):71-8.
- Vidrine DJ, Arduino RC, Gritz ER. Impact of a cell phone intervention on mediating mechanisms of smoking cessation in individuals living with HIV/AIDS. Nicotine Tob Res. 2006 Dec;8 Suppl 1:S103-8.

In addition, the use of reminder systems for tobacco cessation is recommended by the CDC Task Force on Community Preventive Services, whether used alone or as part of multi-component intervention.

Job Creation

1. How many jobs has the program created? Are those jobs government or private sector jobs?

Communities Putting Prevention to Work will put people to work reducing tobacco use and obesity by expanding opportunities for physical activity and improved access to nutritious foods and beverages in schools, workplaces, and other settings.

Communities Putting Prevention to Work awards to states and communities are expected to create jobs in the public health and private sectors, through subcontracts to local businesses and nonprofit organizations in support of program goals.

Recipients of Recovery Act awards are required to report quarterly on the number of jobs paid for with Recovery Act funds with a specified formula provided by the Office of Management and Budget (OMB). Recipients are required to submit quarterly reports to the Recovery Accountability and Transparency Board's FederalReporting.gov system, containing a direct and comprehensive count of jobs created and the number of jobs retained by the project or activity as prescribed in Section 5 of OMB guidance M-09-21.

2. In the proposals submitted, were grant applicants required to estimate how many jobs they would create?

The Funding Opportunity Announcements (FOA) stated that recipients of the Recovery Act funds must comply with all requirements specified in Division A of the Recovery Act (Public Law 111-5), including reporting requirements outlined in Section 1512 of the Act and designated Recovery Act outcome and output measures.

Recipients are required to submit quarterly reports to FederalReporting.gov, containing a direct and comprehensive count of jobs created and the number of jobs retained by the project or activity as prescribed in Section 5 of the Office of Management and Budget (OMB) guidance M-09-21. Recipients are required to use a specified formula provided by OMB, which is based on actual number of hours worked. See Section 5.3 of the OMB guidance for more information on calculating jobs, including job estimation examples. For the full OMB guidance, please visit: http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09-21.pdf

3. Was job creation a factor in the decision making process that selected grant award recipients? If yes, how big of a factor was it?

CDC adheres to a defined and rigorous process for selecting all grantees. Applications were scored by objective review panels using the evaluation and scoring criteria published in the Funding Opportunity Announcements (FOA). Job creation was not included in the application review criteria, since it was not in the published review criteria in the FOA. Per the published criteria, applications were scored on the extent to which the proposed plan provided a robust combination of interventions with broad reach, and provided evidence that the applicants' plans were likely to produce the long term outcomes of the Communities Putting Prevention to Work Program. Applications were evaluated against the following criteria: program infrastructure and fiscal management, leadership team and community coalitions, intervention area, community action plan, and intervention strategies, plan for project monitoring and evaluation, and programmatic support needs.

Applications were reviewed for responsiveness by CDC's Procurement and Grants Office (PGO) and the National Center for Chronic Disease Prevention and Health Promotion.

4. Can you provide the Committee with the total number of jobs that the grant recipients promised to create?

Applicants were not required to estimate the total number of jobs that will be created and/or saved in their application.

Recipients of Recovery Act awards are required to report quarterly on the number of jobs paid for with Recovery funds with a specified formula provided by the U.S. Office of Management and Budget (OMB). Recipients are required to submit quarterly reports to HHS containing a direct and comprehensive count of jobs created and the number of jobs retained by the project or activity as prescribed in Section 5 of the Office of Management and Budget (OMB) guidance M-09-21.

Each funded State, Territory, and community will calculate jobs based on the actual number of hours worked and report this to federal reporting gov. CDC expects to have figures on jobs created and/or saved after the FY 2010, Quarter 3 reporting period in July 2010. Data from the FY 2010, Quarter 3 reporting period will be available publicly in early August 2010.

5. What are the oversight tools HHS (and the CDC) has in place to ensure that the grants are spent to create the jobs promised?

The American Recovery and Reinvestment Act guides HHS and CDC regarding obligations to provide oversight for job creation. The ARRA reporting requirements provide a helpful structure to ensure oversight and appropriate use of federal funds. Grantees are required to comply with all reporting requirements specified in Division A of the Recovery Act (Public Law 111-5) including reporting requirements outlined in Section 1512 of the Act and designed Recovery Act outcome and output measures. Section 1512 requires grantees to provide an estimate of the number of jobs created and the number of jobs retained by the project or activity as specified by Office of Management and Budget (OMB) Guidance M-09-21 (June 22, 2009). HHS and CDC will review this data quarterly as reported by recipients on federalreporting.gov.

Lobbying

1. How can the CDC both charge grant recipients with "supporting" and "implementing" "legislative and regulatory" policy changes while at the same time commanding them to "be careful to prevent CDC funds from being used to influence or promote pending legislation"?

Communities Putting Prevention to Work provides states and localities with resources to create healthy environments for residents, such as increasing availability of healthy foods and beverages, improving access to safe places for physical activity, discouraging tobacco use, and encouraging smoke-free environments.

Communities Putting Prevention to Work accomplishes this by supporting communities in their work to promote policy, systems, and environmental changes which result in sustainable improvements in public health. Work on policy, systems, and environmental change encompasses a wide range of community activities.

Policy change includes many types of strategies that do not require legislative or regulatory changes. Examples of policy that do not involve changing laws include school districts choosing to require daily physical education for their students, local businesses implementing smoke-free work place policies, and cities and towns working with vendors to ensure healthy food options in vending machines in government buildings.

Changing systems for the better is also an effective way to improve health and wellness in our communities. Systems are all around us court systems, systems of care, agricultural systems, and business organization systems. Examples of systems changes include farm to table initiatives such as increasing the number of farmers markets in a community or using locally grown fruits and vegetables in meals prepared by local schools; hospital systems supporting and encouraging breastfeeding for patients and employees in the hospital, at home, and in the community; and providing multiple links and referrals to smoking cessation services across government systems (e.g. at the Department of Motor Vehicles or when applying for public benefits).

Similarly, our health and well-being is impacted by our immediate surroundings and our extended environment. Some communities are working with urban planners to increase the number of sidewalks and bike paths in a city or town to promote physical activity. Others are encouraging traffic calming strategies that improve safety for pedestrians and bicyclists, such as narrowing traffic lanes, adding bike lanes, and planting trees along the street. Many communities are engaging with law enforcement to improve safety in public parks and increase access to safe places to exercise.

2. Have grant recipients been told how important it is they do not violate federal lobbying restrictions? What exactly have they been told?

- All CDC grantees including the Communities Putting Prevention to Work grantees are educated
 on all federal laws relating to funding awards including applicable anti-lobbying provisions.
 Specifically, CDC Additional Requirement (AR) 12 entitled "Lobbying Restrictions" is set forth
 in the Funding Opportunity Announcement and lays out in detail the restrictions on applicants'
 use of HHS funds for lobbying. (Funding Opportunity Announcement CDC-RFA-DP09012ARRA09. See specifically, SectionVI.2, Administrative and National Policy Requirements,
 Additional Requirement 12.)
- Funded communities were explicitly reminded of the prohibition against using federal funds for lobbying activity on an all-hands budget call on Tuesday, February 17, 2010.
- The Notice of Grant Awards sent to communities on March 18, 2010 again included written
 notice about the prohibition against using federal funds for lobbying activity. (See note 16 in the
 Notice of Grant Awards).
- CDC reiterated the prohibitions against lobbying at the program kick-off meeting in April, including a presentation by a representative from the U.S. Department of Health And Human Services Office of General Counsel, who directed all the communities to the Additional Requirement 12 for additional guidance.

3. Are grantees expected to be able to meet the policy goals of getting legislation and regulations passed without lobbying? How?

Generally, Federal law prohibits the use of federal funds to lobby a member of Congress, a jurisdiction, or an official of any government, to favor, adopt, or oppose any legislation, law, or policy whether before or after its introduction or to engage in indirect or "grass roots" lobbying. Anti-lobbying provisions, however, do not prevent communication designed to educate officials or the public regarding the science, nor do they prevent agencies from communicating to officials at their request or to Congress through the proper official channels. All CDC grantees are educated on all federal laws relating to funding awards including applicable anti-lobbying provisions. Specifically, CDC Additional Requirement (AR) 12 entitled "Lobbying Restrictions" is set forth in the Funding Opportunity Announcement and lays out in detail the restrictions on applicants' use of HHS funds for lobbying.

The prohibition against lobbying does not mean that communities are prohibited from interacting with policy makers such as legislators in order to promote the goals of the Communities Putting Prevention to Work program. There are many activities that are allowable under federal law which community leaders may decide to pursue. Public health organizations nationwide including CDC – regularly engage in these activities as part of their normal duties and responsibilities.

Some examples of allowable activity include:

- Publishing and disseminating research and public health surveillance data
- Responding to requests from legislators for analysis of public health implications of
 potential or pending legislation
- · Providing information about a specific public health issue
- At the invitation or request of a legislator, representing the health agency before a legislative committee
- Promoting public health interventions through education, coalition-building, and partnerships

4. Do "education campaigns" that support specific policy goals – like soda taxes and zoning restrictions – violate the federal anti-lobbying policy?

No, education campaigns that support specific policy goals do not violate the federal antilobbying policy. It is the obligation and responsibility of public health professionals to widely disseminate to both the public and policy makers the latest information on evidence and practicebased strategies shown to be effective in preventing disease and promoting health. For example, there is no question that raising the price of tobacco products is effective in reducing tobacco use and therefore the burden of tobacco-related disease and death. It is incumbent upon public health professionals to share such evidence-based information with the public and policy makers to improve and protect the health of communities while still complying with the lobbying restrictions. 5. What oversight mechanisms does the CDC have in place to ensure that grant monies are not used to lobby?

The Communities Putting Prevention to Work program has a robust plan for performance monitoring in order to insure that federal funds are used effectively and appropriately. The plan is designed to ensure CDC staff are positioned to identify early warning signs that a program is falling off track or using federal funds for unauthorized and inappropriate activities.

An electronic performance monitoring system provides a central repository for collecting information from a number of program monitoring sources:

- 1) Budget Reviews and Reviews of Community Action Plans and State/Territory Work Plans
- 2) Project Officer Monitoring System that includes instructions derived from a number of sources including a tracking sheet of outcome objectives and key milestone activities that are completed quarterly by each Project Officer, including: monthly conference calls and project management reports, annual site visit reports completed by Project Officers and submitted to the record at CDC's Procurement and Grants Office (PGO) upon return from each site visit, substantive correspondence providing support, and reports submitted to PGO as part of the record such as budgets, personnel, community action plans, etc.

In addition to the robust performance monitoring described above, PGO provides additional and specific budgetary oversight to ensure the appropriate use of federal funds. PGO staff will participate in annual site visits to all funded communities.

6. Are grantees required to certify that they have not used any funds for advocacy and lobbying efforts — either direct or indirect lobbying? Will you require this?

Grantees are required to certify that they will not use fund for lobbying at the time they apply for funding from CDC. The Funding Opportunity Announcement provided a link to the full text of the certification and assurances that grantees agree to when they sign the application.

(http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm). Please see the actual certification language below.

"3. Certification Regarding Lobbying

Title 31, United States Code, Section 1352, entitled "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," generally prohibits recipients of Federal grants and cooperative agreements from using Federal (appropriated) funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a SPECIFIC grant or cooperative agreement. Section 1352 also requires that each person who requests or receives a Federal grant or cooperative agreement must disclose lobbying undertaken with non-Federal (non-appropriated) funds. These requirements apply to grants and cooperative agreements EXCEEDING \$100,000 in total costs (45 CFR Part 93).

The undersigned (authorized official signing for the applicant organization) certifies, to the best of his or her knowledge and belief, that:

- (a) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
- (b) If any funds other than Federally appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.
- (c) The undersigned shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure."

Applications

1. Please provide copies of all grant applications that were selected for awards.

As requested, copies of the applications will be provided to Earley Green, Chief Clerk, Committee on Energy and Commerce. Due to the large size of the files, compact discs containing the funded State and community applications will be provided to Earley Green by our CDC Washington office.

Please note that these are the original applications submitted by the States, Territories, and communities, and the funded activities may differ substantially from those outlined in the applications. To the extent that proposed activities violate the anti-lobbying provisions, such activities have not been and will not be funded by the CDC under this award. CDC is still providing technical assistance to some grantees to finalize their revised work plans and to ensure that all activities are in compliance with Federal law.

Reports Submitted to the Appropriations Committees

- The stimulus bill requires that the Secretary of HHS provide both the House and Senate
 Appropriations Committees with an "operating plan for the Prevention and Wellness Fund
 prior to making any Federal obligations of funds."
 - a. Was the operating plan submitted?

Yes

b. When was it submitted?

On May 15, 2009, HHS submitted a preliminary operating plan consistent with the Recovery Act's mandate to submit required operating plans for the Prevention and Wellness Fund within 90 days of the law's enactment. HHS transmitted a final operating plan on September 16, 2009

c. Would you provide a copy of the operating plan?

As requested, a copy of the final operating plan is attached to this response.

- The bill also requires the Secretary of HHS to update the Appropriations Committees with a report on the actual obligations, expenditure, and unobligated balances for each activity not later than November 1, 2009 and every 6 months thereafter. That would mean that the second report is due on May 1st.
 - a. Was the November report submitted to the Appropriations Committees on time?

Yes

b. Please provide a copy of the November report.

As requested, a copy of the November report is attached to this response.

c. Please provide a copy of the upcoming May report.

As requested, a copy of the May report is attached to this response.

Fast Food Density

1. What exactly is the CDC suggesting that states and localities do if they want to use zoning to reduce the density of fast food establishments?

Zoning may be a feasible strategy for reducing exposure to unhealthy foods and improving diet quality based on science that indicates those who live in areas with greater exposure to fast food outlets near their home are 11%-61% more likely to eat fast food and 3%-17% less likely to have a healthy diet (Moore et al AJE 2009). There is also evidence to show that those never eating fast food are 2-3-times more likely to have a healthy diet versus those eating fast food 1 or more times per week (Moore et al AJE 2009).

CDC suggests that states and communities considering zoning to reduce the density of fast food establishments use the resources listed below to aid them in their efforts.

The Strategic Alliance has an ENACT database for local policies. Searching with the key term "fast food," will list the different communities that have enacted policies around fast food. http://eatbettermovemore.org/sa/policies/search_results.php?s_Search=fast+food+

Other Resources:

The City Planner's Guide to the Obesity Epidemic: Zoning and Fast Food http://www.publichealthlaw.net/Zoning%20City%20Planners%20Guide.pdf

The Use of Zoning to Restrict Fast Food Outlets: A Potential Strategy to Combat Obesity, from The Center for Law and the Public's Health at Johns Hopkins and Georgetown Universities http://www.publichealthlaw.net/Zoning%20Fast%20Food%20Outlets.pdf

The City of Detroit, MI, requires a minimum distance of 500 ft between specified standard, carryout, fast-food and drive-in restaurants and elementary, junior high and high schools. http://www.preventioninstitute.org/sa/policies/pdftext/Detroit-Zoning%20and%20Fast%20Food.pdf

American Planning Association: Policy Guide on Community and Regional Food Planning. http://www.planning.org/policy/guides/adopted/food.htm (HTML version)

http://www.planning.org/policy/guides/pdf/foodplanning.pdf

"A Planners Guide to Community and Regional Food Planning: Transforming Food Environments, Facilitating Healthy Eating" by Samina Raja, Branden Born & Jessica Kozlowski Russell, 2003. http://myapa.planning.org/apastore/Search/Default.aspx?p=3886&a=1003.

Planning for Healthy Places explores community planning solutions to increase access to healthy foods and physical activity through improvements to the built environment. http://www.healthyplanning.org/

"Access to Affordable and Nutritious Food: Measuring and Understanding Food Deserts and Their Consequences." United States Department of Agriculture (USDA), June 2009. http://www.ers.usda.gov/publications/ap/ap036/

The Food Environment Atlas, a web-based mapping tool developed by USDA's Economic Research Service, currently assembles information on over 90 indicators of the food environment, including number of food stores and restaurants and expenditure on fast foods. Data is available by county. http://ers.usda.gov/FoodAtlas/about.htm

Selected Journal Articles:

Moore LV, Diez Roux AV, Nettleton JA, Jacobs DR, and Franco, M. Fast-Food Consumption, Diet Quality, and Neighborhood Exposure to Fast Food: The Multi-Ethnic Study of Atherosclerosis. American Journal of Epidemiology. 2009

Austin SB, Melley SJ, Sanchez BN, et al. (2005). Clustering of Fast Food Restaurants Around Schools: A Novel Application of Spatial Statistics to Study of Food Environments. American Journal of Public Health, 95(9):1575-1581

Crawford D, et al. Neighborhood fast food outlets and obesity in children and adults: the CLAN Study. International Journal of Pediatric Obesity, 2008; 1

Macdonald, L. Neighborhood fast food environment and area deprivation-substitution or concentration? Appetite 2007; 49: 251-254

Sturm, R. Body mass index in elementary school children, metropolitan area food prices and food outlet density. Public Health 2005; 119: 1059-1068

Currie, J. DellaVigna, S, Moretti E, Pathania V. The Effect of Fast Food Restaurants on Obesity. Food planning Digest January, 2009; 52 (20). http://www.econ.berkeley.edu/~sdellavi/wp/fastfoodJan09.pdf

National Policy and Legal Analysis Network; Model Healthy Food Zone Ordinance, http://www.nplanonline.org/nplan/products/model-healthy-food-zone-ordinance

National Policy and Legal Analysis Network; Creating a Healthy Food Zone Around Schools, http://www.nplanonline.org/nplan/products/creating-healthy-food-zone-around-schools

2. Under this strategy would it be appropriate for a zoning law to permit only 5 total fast food establishments within a 1 mile radius of any school?

Communities have full discretion to determine the extent and use of zoning as a component of this strategy to address access to healthy food.

American Recovery and Reinvestment Act Communities Putting Prevention to Work

1. Purpose of Funding

The American Recovery and Reinvestment Act of 2009 states that "\$650,000,000 shall be provided to carry out evidence-based clinical and community-based prevention and wellness strategies authorized by the Public Health Service Act . . . that deliver specific, measurable health outcomes that address chronic disease rates." The Department of Health and Human Services (HHS) has proposed a robust initiative in response to the Act. The goal of this initiative — Communities Putting Prevention to Work — is to reduce risk factors and prevent/delay chronic disease and promote wellness in both children and adults. Communities Putting Prevention to Work will expand the use of evidence-based strategies and programs, mobilize local resources at the community-level, and strengthen the capacity of states. The initiative has a strong emphasis on policy and environmental change at both the state and local levels and will: (1) increase levels of physical activity; (2) improve nutrition; (3) decrease obesity rates; and (4) decrease smoking prevalence, teen smoking initiation, and exposure to second-hand smoke. Powerful models of success are expected to emerge to inform health reform.

Recipients will put the following five strategic interventions into practice (MAPPS Interventions), described in a community tobacco plan or obesity, physical activity and nutrition plan:

- Use <u>media</u> to promote healthy foods/drinks and increase activity; restrict advertising and employ counter-advertising for tobacco and unhealthy foods/drinks;
- Increase <u>access</u> to healthy food/drink choices and safe locations to be active and improve the built environment; reduce the availability of tobacco and unhealthy food/drinks;
- <u>Use of point of decision</u> labeling/signage/placement to discourage consumption of tobacco, increase consumption of healthy foods/drinks, and prompt physical activity;
- Use <u>price</u> to discourage consumption of tobacco and to benefit consumption of healthy foods/drinks; and
- Use <u>social support/services</u> to promote tobacco cessation, breastfeeding, and increased activity.

2. Means of Execution

Community Program (\$449.4 million; 69.1%) – The Centers for Disease Control and Prevention (CDC), will support intensive community approaches to chronic disease prevention and control in selected communities (urban and rural), to achieve the following prevention goals:

- Increased levels of physical activity;
- Improved nutrition (e.g. increased fruit/vegetable consumption, reduced salt and transfats);
- Decreased overweight/obesity prevalence
- Decreased smoking prevalence and decreased teen smoking initiation; and
- Decreased exposure to secondhand smoke.

The five evidence-based MAPPS strategies (media, access, point of decision information, price, and social support), when combined, can have a profound influence on improving health behaviors by changing community environments. Communities will implement a focused set of prescribed interventions, to be outlined in the funding opportunity amouncement, in tobacco and/or obesity and related risk factors to achieve broad reach, high impact, and sustainable change. The specific amount of funding per community will be determined by mix of interventions, population size, ability to reduce health disparities, and likelihood of success. The official local, state or tribal health department (or its bona fide agent, equivalent, or other fiscal intermediary as designated by the mayor, county executive, or other equivalent governmental official), will serve as the lead/fiduciary agent on behalf of an effective community-wide consortium. Consortium partners could include local and state health departments and other governmental agencies, health centers, schools, businesses, community and faith-based organizations, academic institutions, and health care providers. Mental health/substance abuse organizations, health plans and other community partners working together to promote health and prevent chronic diseases are encouraged.

Applicants should clearly articulate how activities will be sustained after Recovery Act spending is complete. Applicants will also be asked to demonstrate through letters of support that they have political support and connections with other community development and livability efforts, and that they build on and leverage existing place-based revitalization and reform projects funded by the US Government, including the US Department of Health and Human Services (HHS), and programs supported by other agencies such as the US Department of Housing and Urban Development, the Environmental Protection Agency, the US Park Service, US Department of Transportation, US Department of Agriculture, the Corporation for National and Community Service, and the US Department of Education. Applicants will also be encouraged to coordinate with other US Government-funded Recovery Act efforts in multiple sectors, such as transportation, education, health care delivery, agriculture and others, as well as coordinating with HHS Regional Offices.

This component also includes a robust support plan to ensure funded communities are successful, and that the agencies are able to evaluate the impact of their efforts. The plan consists of a three-pronged approach:

- (1) Community Programmatic Support (\$27.1 Million) intervention design, expertise, implementation support, and national dissemination and training. These activities will occur before, during, and after the program implementation period. Elements of this support will be embedded in communities based on community needs;
- (2) Community Mentoring (\$10.0 Million) fund up to 10 communities to provide mentoring to less experienced communities based on their previous success in specific policy strategies; and
- (3) Evaluation (\$39.5 Million) through a multi-component evaluation strategy that includes community and state level risk factor surveillance, case studies in funded communities and states, cost tracking, and modeling. Plans will focus on a small set of behavioral outcomes linked to chronic disease and community-level policy and environmental change. Program logic models will be developed to illustrate how the set of chosen interventions and the processes encompassed by these interventions will drive outputs which, in turn, will drive the policy/environmental and

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behavioral outcomes of interest. These models will guide decisions about what aspects of interventions, outputs, and outcomes to measure. Modeling will also be used to extrapolate the expected impact of expected proximal outcomes to make progress during the duration of the funding on the more distal chronic disease outcomes for which change may not be seen until later. Behavioral outcomes will be tracked using existing BRFSS and YRBSS tools, and the CDC CHANGE Tool data collected in funded communities. Applicants will be asked to participate in monitoring and evaluation efforts within funded communities, including pre and post measurement. This includes the use of biometric measurements for those applicants who wish to improve the quality of those efforts, already in place, as they relate to collection of height and weight in school-age children and youth.

National Prevention Media and National Organizations Initiative (\$40.0 million; 6.2%) — To foster effective and hard-hitting prevention and wellness messages and advertisements, investments will be made by the CDC in national media to provide communities with high-quality communications expertise to assist in achieving measurable health outcomes. Communications materials will be tailored to address the unique needs of communities and will provide materials and templates to give the initiative a powerful brand. The communications component will draw on the full array of materials available across HHS, the Federal Government, and non-governmental organizations, ensure consistency and quality, provide support, and aggregate outreach materials so that they can be easily and widely accessed. National organizations will be funded as part of the effort to support community outcomes. Under the direction of CDC and HHS Office of Public Health and Science, this nationally coordinated investment will focus on community-linked prevention and wellness media.

States and Territories (\$157.3 million; 24.2%) – The total initiative has three major State and Territory components:

- (1) Policy and environmental change (\$75 million) under direction of CDC, states will receive funding to promote state-wide policy and environmental changes in support of the goals of this initiative. These policy activities, applying the five strategies, will support and institutionalize healthy behaviors related to nutrition, physical activity, obesity control and tobacco use. Strategies should be grounded in evidence. All states and territories will be eligible for a base funding amount determined by population, and additional competitive funds for special policy initiatives;
- (2) Tobacco cessation (\$50 million) under direction of CDC, all currently funded states and territories will be eligible to apply for and expected to receive funding to expand tobacco quit lines, in concert with expanded media campaigns. States and territories would receive funding based on the number of smokers in their jurisdiction. Additional funds will be used for national efforts to support surge capacity, additional quit line monitoring and quality improvement measures; and
- (3) Chronic disease self-management program (CDSMP) (\$32.5 Million) expands the Administration on Aging (AoA) and Centers for Disease Control and Prevention (CDC) partnership to leverage the public health and aging networks at the state and community level to deploy evidence-based prevention programs targeted at the elderly.

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States will have the option of applying for funds, and Governors will decide through which state government entity the funding would flow (State Units on Aging or State Health Departments). Regardless of which state agency is designated the lead; these projects must involve a full partnership between the public health and aging networks. Applicants will be asked to include sustainability plans in their applications for the Chronic Disease Self-Management Program. Outcomes will be measured and tracked using program milestones, a pre- and post survey of participants to measure changes in behaviors and health status, and self reported hospital use a prototype system will be developed and tested for using Medicare claims data to track the actual health care utilization of participants served through these program and comparing it with the claims data of comparable groups of Medicare beneficiaries who did not participate in the program. States will subsequently be able to use this system as part of their own quality assurance programs.

Management and Oversight (\$3.25 million; 0.5%)

A total of \$3.25 million will be used for management and oversight of the entire Communities Putting Prevention to Work initiative. This amount is equal to 0.5% of the \$650 million appropriated for the initiative: \$3,087,500 for CDC and \$162,500 for AoA.

3. Method of Selection

Activity	Method of Selection
Community Program	New competitive funding opportunity announcement,
► Community Awards	new and existing contracts, and supplement to an
► Mentoring Awards	existing funding announcement
► Programmatic Support	
► Evaluation	
National Prevention Media and	New and existing contracts and new funding
National Organizations Initiative	opportunity announcement
States and Territories	Supplement to existing funding announcements and
▶ Policy and Environmental Change	new and existing contracts
► Quitline Efforts	_
►CDSM	

4. Intended Award Recipients

Funds disbursed through this program will be obligated through a combination of new and existing cooperative agreements and contracts, as well as transfers to other operating divisions within HHS. Funds will be awarded in accordance with the applicable provisions of the Recovery Act, and all applicable HHS-specific and government-wide policies related to such actions whether the policies are general or specific to Recovery Act funds.

Activity	Intended Award Recipients
Community Program	Official local, state or tribal health department (or its
► Community Awards	bona fide agent, equivalent, or other fiscal intermediary
► Mentoring Awards	as designated by the mayor, county executive, or other
➤ Programmatic Support	equivalent governmental official) on behalf of an
►Evaluation	established community coalition; contracts; and non-
	profit organizations

National Prevention Media and National Organizations Initiative	Contracts and non-profit organizations
States and Territories ► Policy and Environmental Change ► Quitline Efforts ► CDSM	States, District of Columbia, Puerto Rico and Virgin Islands, Pacific Island Territories; contracts; National Institute of Health; Center for Medicare and Medicaid Services; non-profit organizations; and Universities.

5. Fiscal Year of Expenditure
All funds will be obligated in fiscal year (FY) 2010.

Designation of funding by organizational structure

Funding will be provided to the Centers for Disease Control and Prevention (CDC), the Administration on Aging (AoA), and the HHS Office of this Secretary (OS) for this effort. Funds will be provided to CDC and AoA via Intra-Departmental Delegation of Authority (IDDA) by HHS.

7. Accountability Measures

The Department of Health and Human Services Office of the Inspector General reviewed this spend plan and no significant problems were identified. CDC, AoA, and HHS OS will use the Recovery Act risk assessment tool to be provided by the HHS-Office of Finance to mitigate any risk. In accordance with current practice, there will be frequent communication between grant recipients and program staff, including regular conference calls. Program staff will ensure site visits are conducted according to Recovery Act requirements, and that technical assistance is provided. Approved allowable and unallowable expenditures will be clearly communicated to grantees, according to the statutes and the Federal Acquisition Regulations (FAR).

U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC)

Report on Actual Obligations, Expenditures, and Unobligated Balances American Recovery and Reinvestment Act of 2009 Prevention and Wellness Fund

Thomas R. Frieden, M.D., M.P.H.

Report on Actual Obligations, Expenditures, and Unobligated Balances American Recovery and Reinvestment Act of 2009 Prevention and Wellness Fund

Period Covering February 17, 2009 to September 30, 2009

The American Recovery and Reinvestment Act of 2009, Pub. L. 111-5 (Feb. 17, 2009), Page 180-181:

"PREVENTION AND WELLNESS FUND (INCLUDING TRANSFER OF FUNDS)

For necessary expenses for a "Prevention and Wellness Fund" to be administered through the Department of Health and Human Services, Office of the Secretary, \$1,000,000,000: Provided. That of the amount provided in this paragraph, \$300,000,000 shall be transferred to the Centers for Disease Control and Prevention ("CDC") as an additional amount to carry out the immunization program ("section 317 immunization program") authorized by section 317(a), (j), and (k)(1) of the Public Health Service Act ("PHS Act"): Provided further, That of the amount provided in this paragraph, \$650,000,000 shall be to carry out evidence-based clinical and community-based prevention and wellness strategies authorized by the PHS Act, as determined by the Secretary, that deliver specific, measurable health outcomes that address chronic disease rates: Provided further, That funds appropriated in the preceding proviso may be transferred to other appropriation accounts of the Department of Health and Human Services, as determined by the Secretary to be appropriate: Provided further, That of the amount appropriated in this paragraph, \$50,000,000 shall be provided to States for an additional amount to carry out activities to implement healthcare associated infections reduction strategies: Provided further, That not more than 0.5 percent of funds made available in this paragraph may be used for management and oversight expenses in the office or division of the Department of Health and Human Services administering the funds:... Provided further, That the Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report on the actual obligations, expenditures, and unobligated balances for each activity funded under this heading not later than November 1, 2009, and every 6 months thereafter as long as funding provided under this heading is available for obligation or expenditure.

Background

As requested by the House and Senate Appropriations Committees, the Secretary of Health and Human Services provides semi-annual reports on the actual obligations, expenditures, and unobligated balances for each activity funded by the \$1,000,000,000 Prevention and Wellness Fund. This report includes a description of the prevention and wellness fund activities as well as the requested financial information. This report includes information and activities from February 17, 2009 to September 30, 2009.

Description of Prevention and Wellness Fund Activities

The three activities that comprise the \$1,000,000,000 Prevention and Wellness Fund activities are detailed below:

Section 317 Immunization Program

The American Recovery and Reinvestment Act (Recovery Act) appropriated to the Department of Health and Human Services Office of the Secretary \$300 million and specified that these funds be transferred to the Centers for Disease Control and Prevention (CDC) for its Section 317 Immunization program (Section 317). The Section 317 Program funds 64 immunization programs that include all 50 states, Washington DC, 5 urban areas, the U.S. Territories, and selected Pacific Island nations.

The majority of Section 317 program funds are dedicated to routine childhood programs, with a small portion remaining for adolescent and adult immunization programs. Most children served with Section 317-funded vaccines are under-insured or their parents cannot afford the out-of-pocket costs required to fully vaccinate their children.

The Recovery Act program funds will expand access to vaccines and vaccination services by making more vaccines available, increase national public awareness and knowledge about the benefits and risks of vaccines and vaccine-preventable diseases, and strengthen the evidence base for vaccination policies and programs.

Healthcare-Associated Infections Reduction Strategies

The American Recovery and Reinvestment Act (Recovery Act) appropriated \$50 million to the Department of Health and Human Services (HHS) Office of the Secretary. These funds will be provided to states for the execution and implementation of healthcare-associated infection (HAI) reduction strategies. They will also be used for state prevention activities and enhancing oversight and accreditation of ambulatory surgery centers (ASCs) at the state level.

This program is aligned to the HHS Action Plan to Prevent Healthcare-Associated Infections, which represents a culmination of research, deliberation, and public comment to identify the key actions needed to achieve and sustain progress in protecting patients from the transmission of serious, and in some cases, deadly infections. For more information, visit: http://www.hhs.gov/ophs/initiatives/hai/infection.html.

Traditionally, state health departments have had limited activities or workforce to address HAIs. However, in recent years more than 20 states have passed laws requiring reporting of hospital-specific HAI data to state health departments with public disclosure of hospital infection rates. In 19 states thus far, the CDC's National Healthcare Safety Network (NHSN) has been identified as the tool for reporting and NHSN participation has grown from 300 hospitals nationally to approximately 2,100 hospitals in two and a half years. This program will provide state health departments with the necessary workforce, training, and tools to rapidly scale up to meet this new effort to prevent HAIs, support the dissemination of HHS evidence-based practices within hospitals, support targeted efforts to monitor and investigate the changing epidemiology of HAIs

in populations as a result of new prevention collaboratives, and address overall HHS HAI prevention priorities.

This program will provide funds for improvement of State Survey Agency (SA) inspection capability of ASCs nationwide and also enable SAs to identify and correct infection control deficiencies in these centers.

Evidence-based Clinical and Community-Based Prevention and Wellness Strategies

The American Recovery and Reinvestment Act of 2009 states that "\$650M shall be provided to carry out evidence-based clinical and community-based prevention and wellness strategies authorized by the Public Health Service Act that deliver specific, measurable health outcomes that address chronic disease rates." HHS has proposed a robust initiative in response to the Recovery Act. The goal of this initiative — Communities Putting Prevention to Work — is to reduce risk factors and prevent and/or delay chronic disease and promote wellness in both children and adults. Communities Putting Prevention to Work will expand the use of evidence-based strategies and programs, mobilize local resources at the community-level, and strengthen the capacity of states. The initiative has a strong emphasis on policy and environmental change at both the state and local levels and will:

- (1) increase levels of physical activity;
- (2) improve nutrition;
- (3) decrease obesity rates; and
- (4) decrease smoking prevalence, teen smoking initiation, and exposure to second-hand smoke.

Community and State/Territory Recipients will put the following five strategic interventions into practice, or MAPPS Interventions, described in a community tobacco plan or obesity, physical activity and nutrition plan:

- Use <u>Media</u> to promote healthy foods/drinks and increase activity; restrict advertising and employ counter-advertising for tobacco and unhealthy foods/drinks
- Increase <u>Access</u> to healthy food/drink choices and safe locations to be active and improve the built environment; reduce the availability of tobacco and unhealthy food/drinks;
- <u>Use of Point of decision</u> labeling/signage/placement to discourage consumption of tobacco, increase consumption of healthy foods/drinks, and prompt physical activity.
- Use <u>Price</u> to discourage consumption of tobacco and to benefit consumption of healthy foods/drinks.
- Use <u>Social support/services</u> to promote tobacco cessation, breastfeeding, and increased activity.

Actual Obligations, Expenditures, and Unobligated Balances

The table below shows the total appropriation, as well as obligations, unobligated balances and outlays for these funds through September 30, 2009, the end of Fiscal Year 2009. Note that expenditures are defined as Federal outlays in the table below.

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Table: FY 2009 Recovery Act Prevention and Wellness Fund Appropriation: Obligations and Outlays, As of September 30, 2009^1

Program	Amount Appropriated	Obligations	Unobligated Balance	Outlays
Section 317 Immunization Program	\$300,000,000	\$154,458,870	\$145,541,130	\$30,334,585
Healthcare Associated Infections Reduction Strategics	\$50,000,000	\$40,621,083	\$9,378,917	\$142,861
Evidence-based Clinical and Community-Based Prevention and Wellness Strategies	\$650,000,000	\$0	\$650,000,000	\$0
Total Management and Oversight (non-add)	\$5,000,000	\$305,736	\$4,694,264	\$246,767
Prevention and Wellness Fund Total	\$1,000,000,000	\$195,079,953	\$804,920,047	\$30,477,445

U.S. Department of Health and Human Services Unified Financial Management System validated against the Office of Management and Budget SF 133 and U.S. Treasury report.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health Bethesda, Maryland 20892

May 20, 2010

The Honorable Henry A. Waxman Chairman, Subcommittee on Health Committee on Energy and Commerce House of Representatives Washington, D.C. 20515

Dear Mr. Waxman:

Thank you for the opportunity to testify at the April 14, 2010 hearing entitled "Smokeless Tobacco: Impact on the Health of our Nation's Youth and Use in Major League Baseball" before the Committee on Energy and Commerce Subcommittee on Health.

I appreciate your interest in the health consequences of smokeless tobacco and the impact that media and celebrities' health behaviors have on tobacco use among youth. The enclosed responses to your questions for the record provide additional information on the health implications of smokeless tobacco and NCI's efforts in the area of tobacco cessation.

Thank you again for your interest and support of cancer research at the NCI. Please do not hesitate to contact me for additional information.

Sincerely

Deborah M. Winn, Ph.D.

Deputy Director, Division of Cancer Control

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and Population Sciences

National Cancer Institute

Enclosure

Questions for the Record Hearing on Smokeless Tobacco April 14, 2010

Energy and Commerce Committee Subcommittee on Health

We have heard reports that in Sweden more people are giving up cigarettes and using smokeless tobacco, and that the rate of lung cancer has gone down. What about using smokeless tobacco as a way to help smokers quit cigarettes?

The Swedish data on tobacco use do not support the conclusion that smokeless tobacco aids people in quitting smoking cigarettes or that use of smokeless tobacco has contributed to the decline in lung cancer in Sweden. Sweden has the lowest male smoking prevalence of any European country (14% of adult men are daily smokers)¹ and, not surprisingly, the lowest level of tobacco-related mortality (about half that of the European Union overall).² However, a significant portion of men (19%) report using oral smokeless tobacco, typically in the form of snus, a moist oral tobacco product.³

Advocates of snus maintain that the experience of Sweden demonstrates that snus has served as an effective harm reducing substitute for cigarette smoking in the Swedish population. They argue that the lower smoking prevalence in Sweden, and thus the lower disease rates, can be attributed to the availability of snus and its use in place of cigarettes. Moreover, some advocates claim that snus has acted as an aid to smoking cessation by providing Swedish smokers with an acceptable alternative nicotine delivery product.

However, observing that a downswing in the trends for one behavior (e.g., smoking prevalence) occurred during the same period of time that an upswing occurred in another (e.g., smokeless tobacco) does not imply that one caused the other. Rather, it is likely that many factors played a crucial role in reducing the prevalence of cigarette smoking in Sweden since the 1950s. Cigarette smoking gained popularity relatively late in Sweden, and the smoking prevalence there never reached the levels of some other European countries. In the early 1960s, Sweden was one of the first countries to fund an organized tobacco control effort, including the development of cessation clinics and anti-smoking education programs, and the population also had early access to some nicotine replacement therapies. 4 Changes in popular culture also likely had an impact on smoking behavior and national smoking trends, as popular portrayals of smoking shifted from acceptance to rejection.⁵ Importantly, similar dramatic reductions in smoking prevalence were seen in Swedish women, despite the fact that only 4% of Swedish women use smokeless tobacco³. Additionally, the pattern of decreasing smoking rates with increasing use of smokeless tobacco has not been seen in Norway, where smokeless tobacco use has increased, but cigarette smoking prevalence has remained constant over

Furthermore, there is a serious risk to promoting smokeless tobacco as a substitute for cigarettes, because smokeless tobacco is often a gateway to cigarette smoking among

adolescents. Two studies from the United States illustrate this point. In one study⁶, adolescent boys who used smokeless tobacco (and no other tobacco product) were more than 3 times more likely to be cigarette smokers four years later, compared to boys who used no tobacco products. In the other U.S. study⁷, boys in the 7^{th} to 9^{th} grade who were smokeless tobacco users (with no other tobacco use) were compared to boys who had never used tobacco. After two years, 58% of the boys using smokeless tobacco at the start of the study were cigarette smokers, and the majority were also using smokeless tobacco – i.e., they were dual users. In contrast, among boys who did not use smokeless tobacco initially, only 34% had become cigarette smokers two years later.

What is meant by the term "harm reduction" within the tobacco context?

Harm reduction is generally defined as a program or policy designed to reduce the harms related to an exposure or behavior without requiring complete cessation of the exposure or behavior. Harm reduction strategies include promoting condom use to prevent sexually transmitted diseases, methadone programs for heroin addicts, needle exchange programs for illicit drug users to prevent transmission of HIV and other infections, and use of seatbelts to reduce injuries from auto accidents. While harm reduction approaches are not incompatible with abstinence, they are generally contrasted with programs primarily aimed at prevention or cessation of drug use.

Potential approaches to tobacco harm reduction that have been suggested include modification of cigarettes to reduce emissions of toxicants, counseling smokers to switch to non-combustible tobacco products (smokeless tobacco), and long term use of therapeutic nicotine (normally used only for limited periods as part of a cessation program) to replace nicotine obtained from cigarettes. Therapeutic (or medicinal) nicotine is commonly referred to as nicotine replacement therapy. While none of these strategies have been proven effective in practice, they vary substantially in the amount of evidence supporting them and the potential risks they pose.

In NCI's view, a tobacco product would be "harm reducing" if it actually reduced disease and death for both individuals and the population as a whole. This is an important distinction because even if a tobacco product is shown to reduce an individual's disease risk, the availability of products that claim to reduce harm may have harmful consequences at the population level – causing a greater burden of disease in the population. Examples of potential harmful consequences are: (1) smokers who might otherwise have quit smoking may see products that claim to reduce harm as a viable alternative to quitting; (2) smokers who have quit will return to using tobacco because they think it is safe or safer to do so; (3) youth or adults who otherwise might not have initiated tobacco use will do so because of perceived safety of the products; and (4) smokers who attempt to use smokeless tobacco as means to reduce or stop smoking may instead find themselves using both products.

There are many important differences between tobacco harm reduction and harm reduction around other public health issues. In particular, tobacco harm reduction is

complicated by the involvement of a multi-national industry that aggressively promotes its products and has a well-documented history of misleading consumers regarding the health effects of its products. Any tobacco harm reduction efforts must take in to account potential tobacco industry responses, and how these responses could negatively impact the public's health.

NCI continues to emphasize that (1) all tobacco products are hazardous, (2) there is no safe level of tobacco use, and (3) the only proven way to reduce the enormous burden of disease and death due to tobacco use is to prevent youth from starting to smoke, and to help current smokers to quit. Smokeless tobacco use causes cancer, and other negative health effects; NCI does not support the use of smokeless tobacco as a harm reduction strategy.

Do the limitations of current tobacco cessation strategies justify placing greater emphasis on tobacco harm reduction?

The vast majority of smokers want to quit, and more than half of all Americans who have ever smoked have succeeded in quitting. Data collected by the U.S. Centers for Disease Control and Prevention indicates that 70% of smokers say they want to quit and 41% had made a quit attempt in the previous year. Quitting smoking can be extremely challenging, and only a little more than two percent of smokers successfully quit each year. Tobacco dependence is best viewed as a chronic disease, with periods of remission and relapse, requiring multiple attempts to achieve long term cessation.

However, individual smokers' cessation efforts can be made more effective. While less intensive interventions, such as brief physician advice to quit smoking, produce cessation rates of 5 to 10 percent per year, more intensive interventions that combine behavioral counseling with pharmacological treatment of nicotine addiction, can produce cessation rates of 20 to 25 percent per year. ¹⁰ Moreover, through a combination of anti-tobacco marketing, public education, treatment programs, and policy measures, some countries and U.S. states have achieved low smoking rates. For example, in 2006, the prevalence of cigarette smoking in California was 14.9%. ¹¹ This low prevalence is widely attributed to the state's exemplary comprehensive tobacco control program, which has been in place for more than 20 years.

There is no "magic bullet" for smoking cessation; but most smokers want to quit, and there are effective treatments for tobacco dependence. Therefore, it is crucial to ensure that smokers who want to quit are better informed about and have better access to treatments that can actually help them. Currently, no harm reduction interventions have been proven to be effective. Rather than suggesting that smokers use unproven harm reduction strategies, we should focus on enhancing knowledge of and access to effective treatments and promoting the development of new, more effective interventions.

Some have suggested that declining to endorse smokeless tobacco as a tool of harm reduction without scientific data on its population-wide impact is equivalent to advocating a "quit or die" or "just say no" policy. Do you believe that is an accurate characterization of that perspective? Is that perspective the equivalent to ignoring smokers' individual rights for information or their access to interventions that are proven to reduce risk?

No. Evidence based non-tobacco treatments are already available to help smokers quit and to treat tobacco dependence. At the same time, evidence is lacking to support the effectiveness of any smokeless tobacco product as part of a harm reduction strategy. As with any medical or public health intervention, rigorous evaluation and proven efficacy is required before implementation as a strategy. Similar to pharmaceutical therapies to treat nicotine addiction, harm reduction strategies must be evaluated based on science. Research is underway to measure and understand how purported harm reduction strategies may affect health and tobacco use behaviors. Unless smokeless tobacco is found through rigorous research studies to effectively reduce harm, it is inappropriate to promote smokeless tobacco use as a harm reduction strategy. ¹²

What factors contribute to the harm of a particular tobacco product? What is meant by the "continuum of risk" of tobacco products?

Tobacco products present a continuum of risk, with combusted (burned) tobacco products dramatically increasing susceptibility to a very wide range of health effects, both from their direct use, and from their indirect use (exposure to secondhand smoke). Smokeless tobacco is a cause of oral and pharyngeal, esophageal, and pancreatic cancer; ¹³ and may also increase the risk of heart disease and stroke ¹⁴ and reproductive problems. ¹⁵ Compared with tobacco products, pharmaceutical products that deliver nicotine (patch, gum, etc.) have a low risk of health consequences because they deliver only nicotine and none of the many other hazardous constituents found in tobacco products.

Many factors contribute to the harm caused by a particular tobacco product. One important factor is the inherent risks of the tobacco product itself. Other key factors are tobacco industry marketing for the product and the patterns of product use; importantly, these are interrelated. For example, current marketing for smokeless tobacco products often encourages smokeless tobacco use in places where cigarette smoking is prohibited. Laws that prohibit smoking in workplaces and public places have been shown to decrease cigarette consumption and promote smoking cessation. Marketing smokeless tobacco as a way to circumvent smoking bans is highly likely to promote dual use of cigarettes and smokeless tobacco, and to deter or delay smoking cessation. The effect of such marketing would be that smokeless tobacco use would result in net harm to the individual and the population as a whole. Finally, harm is influenced by the number of people who use a particular product, with those products used by large numbers of people responsible for greater harm at the population level than those used by small numbers of people.

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